University of Alberta

Understanding contributors to lower urinary tract symptoms in hospitalized older adults

by

Kathleen Frances Hunter

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Abstract

The papers of this thesis represent an exploration of potential contributors to voiding dysfunction in older adults. This work is a foundation for a program of research focused on enhancing nursing knowledge related to care for older adults experiencing lower urinary tract symptoms (LUTS) during acute illness and convalescence.

The first paper addresses the interplay of chronic disease and aging on voiding function. Although a number of diseases of aging affect voiding, diabetes was the focus due to high prevalence. Recommendations for assessment and management of diabetic cystopathy in the older person reflect evidence where possible, but little research has been undertaken in this area. As gender specific urological surgery can have unintended long term effects on voiding function in older individuals, the second paper, a systematic review and meta-analysis on conservative management of post-prostatectomy urinary incontinence, is an exploration of this aspect. Conservative interventions described in this review are used to treat many forms of incontinence, but for post prostatectomy incontinence the value remains uncertain and further high quality studies are needed. The third paper focuses on how aging affects pharmacokinetics and pharmacodynamics. Practice recommendations to avoid or minimize pharmacologically induced geriatric symptom syndromes, including LUTS, are discussed. The fourth paper, a feasibility study (N=16), incorporates knowledge acquired from the three previous papers in comparing voiding function and LUTS among older adults undergoing hip arthroplasty. Findings include a non-significant increase in symptoms of frequency, urgency and nocturia among participants at 6 weeks post hospital; and reduced urinary symptom related quality of life for three. This also raises safety concerns around fall risk and unaddressed

infection post hospital. Further research is needed to more completely understand and identify effective strategies to address such risks. In the final chapter, recommendations for nursing theory, practice, education and research arising from this collection of papers are made. Included is a beginning conceptualization of a model for understanding contributors to LUTS in older persons which incorporates the potential influence of an acute hospitalization.

Acknowledgements

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I wish to extend special thanks to Dr. Katherine Moore, who acted as both supervisor and mentor as I strived to complete this work.

Dedication

For those extraordinary young women in my life, my daughters Laura, Linda and Erin; and my parents Helen Campbell Ballantine Hunter and the late Leslie Albert Hunter.

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List of Nomenclature and Abbreviations

DC – diabetic cystopathy

LUTS – lower urinary tract symptoms. As per the International Continence Society report on standardisation of terminology of lower urinary tract function (Abrams et al., 2002), symptoms are those indicators of disease which are subjective and perceived by the individual, caregiver or partner. These include: storage symptoms (daytime frequency, nocturia, urgency, urinary incontinence, bladder sensation), voiding symptoms (slow stream, spitting/spraying, intermittency, hesitancy, straining, terminal dribble), and post micturition symptoms (feeling of incomplete emptying, post micturition dribble). As well, the ICS has defined several symptom syndromes suggestive of lower urinary tract dysfunction which are relevant to the concerns of older adults including overactive bladder syndrome and lower urinary tract symptoms suggestive of bladder outlet obstruction.

OAB – overactive bladder syndrome

QoL – quality of life

UI - urinary incontinence

UR – urinary retention

Voiding dysfunction – the definition used in this dissertation is in keeping with that described in Wein's Functional Classification (Wein, 2002), which encompasses both phases in the micturition cycle: filling/storage and emptying/voiding. Voiding dysfunction there refers to either (or both) failure to store and failure to empty.

CHAPTER 1

Introduction

Introduction

Voiding issues are commonly encountered conditions among older adults, with urinary incontinence (UI) being considered one of the key geriatric syndromes (Kane, Ouslander, & Abrass, 2004). Both incidence and prevalence of UI increase with age (Cheater & Castleden, 2000; Ostbye et al., 2004). UI is almost twice as prevalent in women compared to men, ranging from 14% of females and 6.3% of males in the 65-69 age group and rising to 29% of females and 16.9% of males over 90 years (Ostbye et al., 2004). In addition to UI, several other bothersome lower urinary tract symptoms (LUTS) (Abrams et al., 2002) are known to become more prevalent with age: nocturia (Hunskaar, 2005; Wagg et al., 2005), symptoms such as intermittency, hesitancy, retention, and terminal dribble suggestive of bladder outlet obstruction in older males, and over active bladder syndrome (OAB). Estimates of the prevalence of OAB with or without incontinence in the general populations of Europe and North America range from 16.6 to 18.1 % (Corcos & Schick, 2004; Milsom et al., 2001; Stewart et al., 2003), and rise steadily with age to 31.3 % of women and 41.9% of men over 75 years (Milsom et al., 2001).

Unfortunately, in spite of being highly prevalent and associated with consequences which could negatively affect physical well being and quality of life, LUTS, like other geriatric symptom syndromes such as immobility and cognitive impairment, remain under recognized and under addressed during hospital stay and discharge (Cheater, 1993; Cooper & Watt, 2003; Norheim & Vinsnes, 2005). This has potential for increasing risks to the individual, as well as potentially contributing to poorer quality of life.

My Interest

My interest in lower urinary tract symptoms and voiding dysfunction in older adults arose from clinical practice in gerontological nursing. It is important at this point to make a clarification of terminology. There is diversity in the literature with concerning the term *voiding dysfunction*. Some use it to refer only to difficulty emptying the bladder. In this dissertation, I use the term as set forth by Wein (2002) in his functional classification of voiding dysfunction, which encompasses both phases in the micturition cycle: filling/storage and emptying/voiding. Voiding dysfunction therefore refers either to or both failure to store and failure to empty. As an advanced practice nurse working with individual patients, I was exposed to quality of life issues and risks to health that develop for individuals with voiding dysfunction and LUTS. As well, nurses would consult me seeking answers to questions regarding management for which only partial answers could be found within existing literature. This kindled my interest in further exploring this area of practice and to seek further preparation in research through doctoral studies.

Background

Overview of Voiding Function

Understanding voiding function is important for the reader of this work to appreciate the connections between the papers of this dissertation. Editorial limitations on manuscript length precludes being able to fully address this within the papers, and so I have included it with the background information. Voiding function has been shown to be modulated by a number of central structures including the pons (pontine micturition and storage centres), periaquaductal gray matter and forebrain (Blok, 2002b; Wagg & Malone-Lee, 1999). The spinal cord plays roles in reflex control of micturition and, as

well, in communication between the brain and lower urinary tract by acting as the central pathway for transmission of efferent and afferent impulses between the two (Blok, 2002a). The lower urinary tract is innervated by autonomic (sympathetic and parasympathetic) and somatic nerves (Chancellor & Yoshimura, 2002). Storage and emptying phases of the voiding cycle are controlled by central (supraspinal) and spinal neural circuits. In normal voiding function, the detrusor (bladder) relaxes and the sphincter (outlet) contracts during the storage phase. In emptying, the detrusor contracts while the sphincter relaxes. Changing from storage to emptying phase can occur both voluntarily and involuntarily (reflex voiding), and the central control of this has been likened to on-off circuit switching of storage and micturition reflexes (Morrison et al., 2002).

Central control and coordination. Central control and coordination allows for the development of voluntary control of voiding function. Cerebral control and central coordination of micturition is not yet completely understood, and both animal and human subject studies have been undertaken. Recent animal studies have shown complex physiology, such as the involvement of multiple neuron types in the pontine storage centre (Sakakibara et al., 2002) and neural communication between the periaqueductal gray and pontine micturition centre in the regulation of micturition (Taniguchi et al., 2002). A review of work relating to the pontine centres cautioned that the similarity of animal micturition centres to human neuroanatomy and physiology is not yet clearly established (Griffiths, 2002). However, the introduction of new imaging techniques has provided opportunity to advance the study of human voiding function. In a study of 17 healthy male subjects using PET scanning (Blok, Antoon, & Holstege, 1997), cortical and

pontine micturition sites, predominantly right sided, where demonstrated, similar to those in cats. Another recently published study using MRI in 12 healthy human subjects supplied further evidence of the involvement of suprapontine structures, including the prefrontal cortex, and the right sided dominance of micturition control (Zhang et al., 2005). Studies involving individuals with central lesions have also enhanced understanding of central voluntary control of voiding. SPECT scanning has shown that decreased frontal lobe perfusion in incontinent, cognitively impaired older adults (Griffiths, McCracken, Harrison, & Moore, 1994b) and global impairment of cortical perfusion (Griffiths et al., 1994a) are associated with urge incontinence and reduced sensation of bladder filling. Frontal lesions are associated with urinary urgency (detrusor overactivity) and impaired detrusor contractility (Sakakibara, Fowler, & Hattori, 1999), while white matter lesions demonstrated on MRI are associated with detrusor overactivity (Sakakibara, Hattori, Uchiyama, & Yamanishi, 1999).

The pons and other higher structures communicate with the lower urinary tract via afferent (sensory) and efferent (motor) nerve fibers extending through or meeting in the spinal cord. The spinal cord is also the location of the motor neurons and sensory interneurons, which along with the brainstem above and ganglion cells in the bladder wall below, compose the micturition reflex (Blok, 2002a). Modulation of the miturition reflex can occur in the sacral level of the spinal cord with control from higher centres. An example of this is Onuf's nucleus in the sacral spinal cord, which is the location of motor neurons extending via the somatic (voluntary) pudendal nerve to the external urethral sphincter (Morrison et al., 2002).

A number of neurotransmitters have been identified, primarily in animal studies, as has having a role in central control of voiding function. Serotonin (Burgard, Fraser, & Thor, 2003), GABA (Blok, 2002b; Morrison et al., 2002) and glycine (Blok, 2002b) are thought to have an inhibitory effect on sensory (afferent) input from the bladder to the brain, thereby suppressing activity of the spinal micturition reflex and regulating bladder volume. Glutamate is an excitatory neurotransmitter in the micturition reflex of cats (Chancellor & Yoshimura, 2002; Morrison et al., 2002), evoking bladder contraction. However, a recent study in rats suggested an inhibitory action on the same reflex in that species (Tanaka, Kakizaki, Shibata, Ameda, & Koyanagi, 2003). Dopamine is thought to have both inhibitory and facilitory effects on the micturition reflex, dependent on the receptor subtype involved (Chancellor & Yoshimura, 2002; Morrison et al., 2002). Adrenergic and cholinergic central pathways have also been identified. There is potential for future pharmaceutical bladder agents based on these neurotransmitters, such as the serotonin/noradrenaline reuptake inhibitor duloxetine (Michel & Peters, 2004; Thor & Dunatucci, 2004), but at this time most bladder agents in act predominantly in the periphery.

Peripheral neural activity in voiding. As mentioned above, the lower urinary tract is innervated by autonomic (sympathetic and parasympathetic) and somatic nerves (Chancellor & Yoshimura, 2002). Sympathetic innervation of the lower urinary tract emerges from the spinal cord at the lumbar region, traveling to the pelvic plexus and urogenital organs via the hypogastric nerve. Parasympathetic innervation emerges from the sacral level of the spinal cord, with parasympathetic fibers traveling in the pelvic nerve to the plexus and organs. Somatic innervation also emerges from the sacral level

through Onuf's nucleus and travels the pudendal nerve to various structures including the external urethral sphincter.

In the peripheral system, primary neurotransmitters are acetylcholine and norepinephrine. During filling, sympathetic nerves primarily release the neurotransmitter norepinephrine, which stimulates bladder neck resulting in outlet contraction. The bladder neck is one area of sympathetic innervation, with males having a richer density of adrenergic receptors at this site than females. The parasympathetic nerves, primarily cholinergic, stimulate detrusor contraction and outlet relaxation, resulting in bladder emptying. The detrusor (bladder muscle) contains muscarinic cholinergic receptors. Nitric oxide has an effect on the autonomic nervous system in the lower urinary tract, producing smooth muscle relaxation at the bladder outlet during micturition (Toda & Okamura, 2003), and may also have a role in bladder afferent sensitivity (Morrison et al., 2002). Acetylcholine is a primary neurotransmitter at somatic neuromuscular junctions.

Aging and Lower Urinary Tract Function

It was helpful for me in approaching the study of voiding dysfunction and LUTS in older adults to work from the perspective of an established model, and as well, to examine literature related to how the aging process affects voiding function. Wein (2002) describes a two-phase functional model for understanding lower urinary tract function: a filling/storage phase and an emptying/voiding phase. This model provides a useful framework for understanding voiding function and identifying potential contributors to dysfunction. Bladder emptying (voiding) requires coordination between contraction of the bladder (detrusor) muscle and relaxation at the outlet. Failure to store urine occurs when there is either decreased outlet resistance or increased bladder (detrusor muscle)

pressure. Failure to empty arises with increased outlet resistance or a decrease in the activity of the detrusor. Incomplete emptying and urinary retention can give rise to voiding symptoms. Acute urinary retention has been associated with risk of renal damage (Mustonen, Ala-Houhala, & Tammela, 1999). Chronic retention also carries risks of renal failure as well as urinary tract infection and a conversion to acute retention (Bates, Sugiono, James, Stott, & Pocock, 2003).

The filling and voiding phases are interdependent, and in older persons with multiple chronic conditions, the situation can be complex, with failure to store and failure to empty urine coexisting (Fonda et al., 2002; Sutaria & Staskin, 2000). An example of this is the syndrome of detrusor hyperactivity with impaired contractility (DHIC) (Resnick & Yalla, 1987), in which the person experiences frequent involuntary detrusorcontractions but is at risk for an elevated post void residual (PVR) urine as the inadequate detrusor contractions are ineffective.

With aging, it is thought that a decline in bladder contractility, decrease in urine flow rate and an increase in post void residual urine occur (Dubeau, 2006; Wagg, 2000), along with a possible reduced bladder capacity (Wagg, 2000). However, separating out normal changes of aging from disease effects is often difficult. For examples, authors of a recent urodynamic study of community based women challenged the idea that decline in bladder capacity is an age change, and suggested it may instead be a result of detrusor overactivity (Pfisterer, Griffiths, Schaefer, & Resnick, 2006). Still, it is likely that there is a gender independent aging process which affects the lower urinary tract, as storage symptoms such as urgency and frequency do not appear to differ between aging males

and females (Araki et al., 2003). Understanding the effect of aging on the urinary tract is not yet complete.

Some of what we understand about the aging bladder comes from animal studies. These have suggested decline in contractility associated with changes in smooth muscle cell membranes, leading to thickening of detrusor smooth muscle (Woodman et al., 2004), increased collagen in smooth muscle (Wu, Baskin, Blakey, Goodman, & Cunha, 1999), decreased muscarinic cholinergic receptors (Pagala, Tetsoti, Dheeraj, & Wise, 2001), decline of mitochondrial enzyme activity resulting in low energy availability (Lin, Hsu, Yang, & Chang, 2000), and decreased blood flow to the detrusor (Saito, Ohmura, & Kondo, 1999). Decreased endothelin autonomic receptors have also been demonstrated in aging rabbit detrusor muscle (Saito, Latifpour, & Weiss, 2000; Wada et al., 2000). Translation of these studies to human bladder aging is not yet clearly established.

However, earlier work in human detrusor biopsies have also found a decline in cholinergic nerves (Gilpin, Gilpin, Dixon, Gosling, & Kirby, 1986) and collagen reorganization (Levy & Wight, 1990) in older subjects compared to younger. Elbadawi and colleagues (Elbadawi, Yalla, & Resnick, 1993) reported on patterns of change in detrusor biopsies of older subjects suggesting that a "dense band" pattern is the norm of aging. However, more recently Brierly, Hindley, McLarry, Harding, & Thomas (2003) published a study comparing younger persons with older, and concluded that muscle cell disruption was not correlated with age but was more common in those of any age with impaired contractility. Further research is needed in this area to clarify cellular changes in the aging human detrusor.

Post void residual urine (PVR) appears to increase with aging due to the decline in detrusor contractility. Currently, guidelines on what value constitutes normal versus abnormal PVR in older adults are based on expert opinion only. Wagg and Malone-Lee (1998) suggest anywhere from 100-200 ml is acceptable, and a more recent review suggested over 200 ml is abnormal (Fonda et al., 2002). Establishing norms of voiding function in older adults is challenged by the difficulty of separating the effects of aging from those of age related disease giving rise to voiding dysfunction.

Personal Health and Economic Consequences of LUTS in Older Persons

In studies involving older adults across a variety of settings, urinary incontinence (Brown et al., 2000; Gluck, Wientjes, & Rai, 1996; Krauss et al., 2005; Kron, Loy, Sturm, Nikolaus, & Becker, 2003; Reyes-Ortiz, Al Snih, & Markides, 2005; Takazawa & Arisawa, 2005; Voaklander et al., 2006), frequency (Krauss et al., 2005), and nocturia (Stewart, Moore, May, Marks, & Hale, 1992) have been associated with increased risk for falls and injury as well as other adverse occurrences. There is little data on specific types of incontinence associated with falls. Among older women, Brown et al. (2000) reported urgency incontinence to be associated with fall risk, but not stress. In contrast, Takazawa and Arisawa (2005) found neither stress nor urgency incontinence alone to be related to falls, but mixed incontinence (both stress and urge) significantly increased fall risk. Economic analysis of the costs of urinary incontinence (Hu et al., 2004) and OAB (Darkow, Fontes, & Williamson, 2005; Hu et al., 2004) have examined both direct treatment costs and the costs of consequences and related comorbidities such as falls, fractures, skin breakdown and urinary tract infection. Using data from a United States

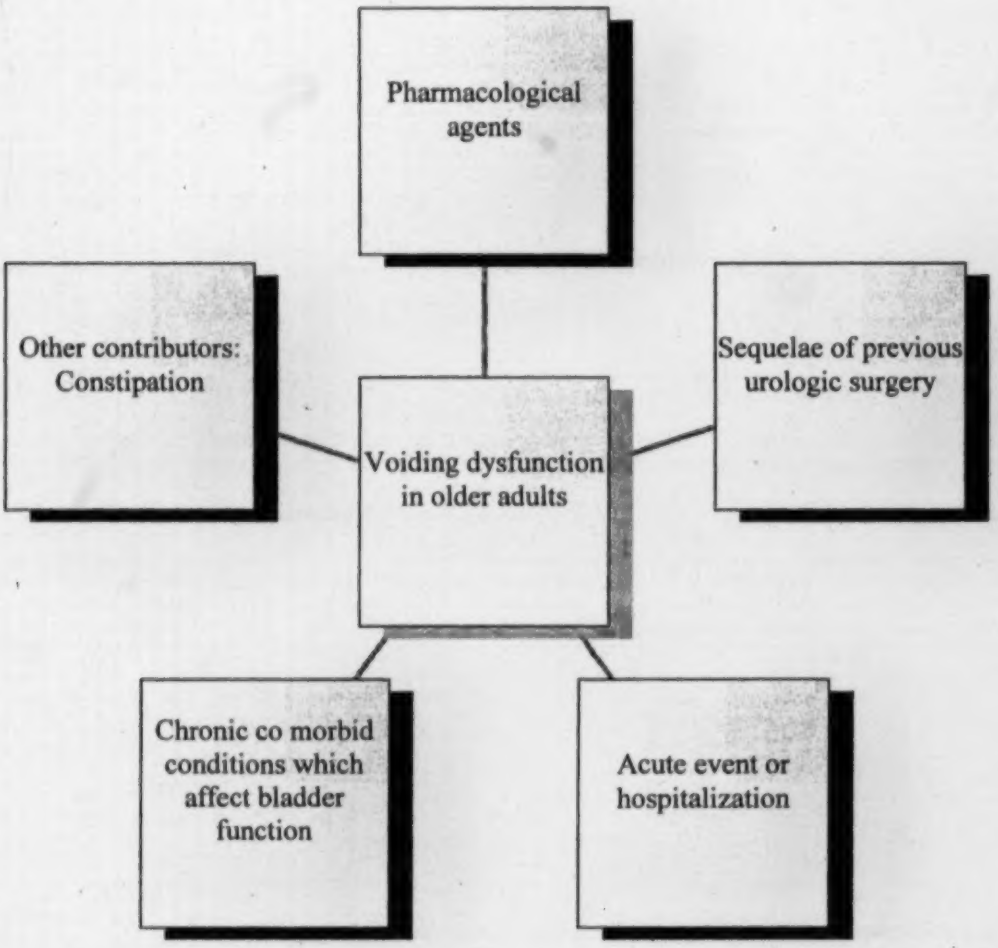
based managed care organization, Darkow (2005) quantified the additional medical costs which occur for patients with OAB compared to those without. Using epidemiological data and a cost of illness framework, Hu et al. (2004) estimated the total yearly direct and indirect cost of UI and OAB in the United States to be $19.5 and $12.6 billion respectively.

In addition to risk of adverse health consequences and increased health care costs, LUTS can have negative effects on the quality of life of older persons. Stewart et al. (2003) reported that persons with OAB were found to have lower quality of life scores, higher depression scores and poorer quality of sleep than those without OAB. Kutner, Schechtman, Ory and Baker (1994) reported UI to be a significant predictor of self-perceived limitations in the usual role activities among community dwelling older adults, and Koyama et al. (1998) found that older female participants with UI limited their participation in group and outdoor activities. Grimby and Savage (1997) reported decreased health related quality of life and stress in daily life in older community based persons associated with a number of diagnostic groups, including UI. In a large (n=3485) study of community-living older adults, UI was independently associated with poor self rated health (Johnson et al., 1998). For spousal caregivers of older adults, UI can have consequences such as role change, financial cost, interference with sleep, social isolation and decreased intimacy (Cassells & Watt, 2003). UI is a predictor of nursing home placement (Thomas et al., 2004; Tilvis, Hakala, Valvanne, & Erkinjuntti, 1995), although many of the older adults placed in long term care also have dementia, underscoring the complex interplay of geriatric syndromes.

The Papers

In my graduate work leading to this dissertation, I explored a number of potential contributors to voiding dysfunction in older adults which, in addition to the aging process, can affect lower urinary tract function. These include chronic co morbidities, sequelae of previous urinary tract surgery, effects of pharmacological agents, and acute illness/hospitalization. Factors outside of the urinary tract and its neurological control mechanisms, such as physical and cognitive function, were not included as their effect on the symptom of urinary incontinence is indirect. In Figure 1, the relationship of these papers as I initially envisioned this work is presented. The papers that comprise this dissertation are the foundation for a program of research focused on enhancing nursing knowledge related to care for older adults experiencing LUTS and voiding dysfunction during acute illness and convalescence.

Figure 1-1. Initial conceptualization of potential contributors to voiding dysfunction in older adults


Pharmacological agents
Other contributors: Constipation
Sequelae of previous urologic surgery
Voiding dysfunction in older adults
Chronic co morbid conditions which affect bladder function
Acute event or hospitalization

Paper One

Clinical observation of hospitalized elders with voiding dysfunction and concomitant chronic comorbid conditions led to the development of the first paper in this project. Although a number of the diseases of aging, including diabetes, Parkinson's diseases/Parkinsonism, stroke and dementia, are recognized to having potential effects on voiding function, I chose to initially focus on diabetes as it is highly prevalent. Furthermore, this foundational paper gave me an opportunity to immerse myself in the research literature related to aging of the urinary tract, and to integrate this material with what was known about a specific chronic condition. In the paper, I suggest an approach for assessment of urinary function in the older adult with diabetes, identify gaps in knowledge and suggest potential opportunities for related clinical research.

A version of the paper in this chapter has been published:

Hunter, K. & Moore, K. (2003). Diabetes associated bladder dysfunction in the older adult. *Geriatric Nursing, 24*, 138-147.

Paper Two

The second paper in this dissertation is a systematic review and meta-analysis on conservative management of post-prostatectomy urinary incontinence. The opportunity to update the review originally undertaken by one of my dissertation supervisors provided not only an exposure to the rigor of the Cochrane methodology, but also to a wide array of literature on UI management strategies.

Gender specific urological surgery can have unintended long term sequelae which may influence baseline voiding function of older individuals. In females, studies of the long term follow-up of anti-incontinence surgery are scarce, with most studies limited to

weeks or months after surgery. A follow-up of women who underwent a variation of the Burch procedure over a 15 year period (mean follow-up period 9.2 years) reported that 374 (74%) of patients required additional surgery later for de novo, persistent or recurring symptoms (Ladwig, Miljkovic-Petkovic, & Hewson, 2004). Another long term follow-up study (N= 441, mean follow-up time 8.6 years) compared incidence of pelvic organ prolapse following two Burch procedure techniques (Langer et al., 2003). In a recent study where two year follow up of the newer TVT procedure was reported, post operative symptoms of lower urinary tract dysfunction, including poor stream, the need to strain to void and the sensation of incomplete emptying decreased after surgery, and maximal flow rate improved (Dietz, Ellis, Wilson, & Herbison, 2004). Work on longer term follow up of this procedure, and treatment of de novo LUTS post surgery, has yet to be completed and published. Although anti-incontinence surgery has been helpful to many women with stress UI for whom conservative treatments such as pelvic floor muscle exercises have been ineffective, incidence of long term complications, and the recurrence of symptoms is not yet clear.

In males iatrogenic stress incontinence can occur post radical prostatectomy (Desautel, Kapoor, & Badlani, 1997; Groutz, Blaivas, Chaikin, Weiss, & Verhaaren, 2000; Gudziak, McGuire, & Gormley, 1996), with damage to the outlet (external sphincter) being a primary etiological factor (Desautel et al., 1997; Peyromaure, Ravery, & Boccon-Gibod, 2002). Incontinence in males post transurethral resection for benign prostactic hypertrophy may be related to coexisting detrusor instability (Fitzpatrick, Gardiner, & Worth, 1979), a bladder related rather than outlet related cause of failure to store. Clinical trials examining interventions for post prostatectomy urinary incontinence

have been published, making it possible to undertake systematic review and meta-analysis in the area.

A version of the paper in this chapter has been published:

Hunter, K. F., Moore, K.N., Cody, J. & Glazener, C. (2004) Conservative management of post prostatectomy urinary incontinence. (Cochrane Review). In: *The Cochrane Library*, Issue 3, 2004. Chichester, UK: John Wiley & Sons UK.

Additionally, a third revision of the review, and version of this paper, has been submitted for review:

Hunter, K. F., Moore, K.N., Cody, J., & Glazener, C. (in review) Conservative management of post prostatectomy urinary incontinence. (Cochrane Review). In: *The Cochrane Library*

Paper Three

The next step was to investigate another of the clinically important contributors to voiding dysfunction, pharmaceutical agents. The third paper addresses how aging affects pharmacokinetics and pharmacodynamics, drug classes of concern in older adults, and challenges to medication use for seniors. As the geriatric symptom syndromes of LUTS, cognitive impairment, falls and impaired mobility are often overlapping in etiology and presentation, this paper was prepared to reflect this. Of particular relevance to voiding function is the table on potential medication induced geriatric syndromes, including voiding dysfunction arising from pharmacologically induced changes to contractility of the bladder or side effects of drowsiness and sedation.

A version of the paper in this chapter has been accepted for publication (October, 2005):

Hunter, K.F. & Cyr, D. (in press). Pharmacotherapeutics in older adults. *JWOCN: Journal of Wound, Ostomy and Continence Nursing*

Paper Four

The fourth paper in this dissertation is a feasibility study examining an approach to the study of voiding issues among older adults undergoing an acute hospitalization and period of convalescence. Undertaking the first three papers provided me with the background knowledge of a number of contributors to voiding dysfunction in older adults. However, I wanted to apply this knowledge to exploring the role that an acute event and hospitalization plays in urinary function. The incidence of new onset or worsening of pre-existing LUTS in hospitalized older adults is not yet well understood, with only sporadic studies in diverse populations having been published. New onset UI has been described as occurring in 21% of older females with hip fracture (Palmer, Baumgarten, Langenberg, & Carson, 2002), with risk factors identified as admission from a nursing home, confusion, prior use of a wheelchair or walking aid, and prior dependence for ambulation. Urinary retention post hospitalization for acute stroke has been observed to improve over a period of rehabilitation (Kong & Young, 2000), although this and other LUTS including nocturia, incontinence, frequency and urgency (Brittain et al., 2000; Sakakibara, Hattori, Yasuda, & Yamanishi, 1996) can persist for months to years after. The incidence of urinary retention in the peri operative period following joint arthroplasty ranges from 0.8 – 54% of patients (Brander, Malhotra, Jet, Heinemann, & Stulberg, 1997; Izard, Sowery, Jaeger, & Siemens, 2006; Petersen, Collins, Selakovich, & Finkbeiner, 1991; Pettrine, Aamlid, & Cabanela, 1991). For older adults, recovery of urinary function after an acute event may be uncertain. In a study of

205 older adults with new onset UI secondary to stroke, orthopedic surgery or illness resulting in deconditioning (Baztan, Arias, Gonzalez, & Rodriguez de Prada, 2005), 40% remained incontinent at discharge from rehabilitation.

Clinically, I had observed numerous people who experienced changes in urinary function while in hospital, and suspected that many issues remained unresolved at discharge. Therefore, as a final step for my dissertation, I undertook a feasibility study to determine if there was evidence to support further research on voiding dysfunction and LUTS, specifically looking at the hospital and convalescent periods. I chose to focus on older adults undergoing hip arthroplasty, as this population is one where data on baseline voiding function and symptoms could be collected before hospitalization. The results of this small study highlight the potential risk and safely issues around falls and infection post hospital, and support further study in this area.

This paper is prepared and ready for submission to JAGS: Journal of the American Gerontological Society:

Hunter, K. F. & Moore, K. N. *Post operative voiding function in older adults undergoing hip arthroplasty: A feasibility study.*

Conclusion: Contribution to Nursing Practice and Theory

Etiology of LUTS in older adults, like any of the geriatric symptom syndromes, is multi-focal and complex. Further research and education of clinicians is needed in order to identify and implement effective interventions which can reduce risk of negative health consequences and associated effects on quality of life. In preparing the papers that comprise this thesis, I have aspired to make a contribution to the literature relating to voiding function in older adults. Individually, the content of some of the papers addresses

clinical assessment and management. As a whole, they are the groundwork for further nursing research and theory development in the overlapping fields of continence and gerontological nursing.

As a clinician, a crucial self-imposed measure of my own work is its relevance to clinical nursing practice and my success in communicating with practitioners. In terms of clinical contribution, the first paper is a unique review and synthesis of research related to the aging of the urinary tract within the context of a chronic condition, diabetes. Basic research is being conducted on the bladder effects of the diseases of aging, including diabetes, Parkinsons/Parkinsonism, stroke and dementia. The knowledge derived from this work is important to symptom management, but most nurses in clinical practice are not in a position to take on extensive review of basic research. Papers such as the first one in this dissertation bring new information derived from research as well as direction for practice change to front line nurses. Published in a premier English language gerontological nursing journal, the manuscript was selected for continuing education unit credit. The second paper on pharmacological agents and their relationships to iatrogenically triggered geriatric symptom syndromes, including voiding dysfunction, is also clinically focused. Broader in scope, the complexity of clinical decision making involved in caring for older adults is illustrated with respect to medications. Basic to nursing care is not only understanding of intended action of pharmacological treatment, but also the side and adverse effects. The contribution of this paper, once published, will be to support nurses in continence practice in linking medication effects to their clinical observations, anticipate care needs, and inform their patients of potential symptoms they may experience.

Bridging clinical practice, theory and research is also key to my work as an advanced practice nurse and researcher. The literature that was explored in developing the two clinical papers, together with the work involved in the systematic review/meta-analysis and feasibility study papers, contribute to nursing theory and research in two ways. First, by understanding further the multi faceted contributors to and consequences of voiding dysfunction in older adults, the need for more sophisticated and better articulated frameworks and theoretical perspectives to guide practice has become increasingly apparent to me. Second, the papers highlight the insufficient knowledge related to assessment and management of LUTS in older adults. The feasibility study is an initial examination of the acute care/convalescent population after a specific procedure. Little is known with regards to LUTS in other groups of older adults who have under gone an acute event. Research is needed to test theoretical linkages between contributors to LUTS and the interplay of other geriatric syndromes as well as the outcomes of clinical assessment and intervention approaches to improve safety and quality of life for older adults with LUTS.

In the final section, the postscript, implications for nursing theory, education, practice and research are articulated. The developing framework for nursing assessment and management of voiding function in older adults who have experienced hospitalization is presented. This framework is an evolution of the initial conceptualization of the influences on voiding function in older adults used to develop the current work, and incorporates additional factors and the linkages among the influencing factors.

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CHAPTER 2

Paper 1: Diabetes Associated Bladder Dysfunction in the Older Adult[1]

Footnote

[1] A version of this chapter has been published

Hunter, K. & Moore, K. (2003). Diabetes associated bladder dysfunction in the older adult. *Geriatric Nursing,* 24, 138-147.

Diabetes Associated Bladder Dysfunction in the Older Adult

The effects of aging on renal function and the lower urinary tract can be exacerbated by superimposed chronic disease, particularly diabetes mellitus. In the US, it is estimated that up to 13% of seniors have diagnosed diabetes (Bertoni, Krop, Anderson, & Brancati, 2002), primarily Type 2, and many more are undiagnosed. While diabetic nephropathy, a life threatening condition, has received considerable attention, diabetic cystopathy (DC) has received less. Yet DC is a chronic complication that affects day to day life, predisposes individuals to urinary tract infections, potentiates renal complications, and poses obstacles to optimum health. It is insidious in onset, characterized by increased length of time between voiding. Prevalence is estimated to be between 32% to 45% (Frimodt-Moller, 1978a; Ueda, Yoshimura, & Yoshida, 1997). In this paper, we discuss age and DC related changes as well as the impact of co-morbid conditions affecting bladder function. An assessment approach to bladder function in older individuals and current management of DC is presented.

Age-Related Changes to the Urinary Tract Function

Cerebral control and central coordination of micturition is complex and not entirely understood. Voiding is mediated by various structures including the pontine micturition center, periaquaductal gray matter and frontal lobe. The spinal cord plays a role in reflex control of micturition and is the central pathway for transmission of efferent and afferent impulses to and from the brain and lower urinary tract. The lower urinary tract is innervated by autonomic (sympathetic and parasympathetic) and somatic (pudendal) nerves, with storage and voiding phases controlled by central (supraspinal) and spinal neural circuits (Morrison et al., 2005). Primary neurotransmitters are

acetylcholine and norepinephrine. The parasympathetic nerves, primarily cholinergic, stimulate detrusor contraction and sphincter relaxation, resulting in bladder emptying. During filling, sympathetic nerves release the neurotransmitter norepinephrine.

Lesions in the cortex, such as those caused by stroke, transient ischemia, or a dementing illness, affect voluntary control due to damage to the centers for cerebral control and coordination of voiding. Decreased frontal lobe perfusion in incontinent, cognitively impaired older adults (Griffiths, McCracken, Harrison, & Moore, 1994b) and global impairment of cortical perfusion, as demonstrated on SPECT scan (Griffiths et al., 1994a), are associated with urge incontinence and reduced sensation of bladder filling. Frontal lesions are associated with urinary urgency (detrusor overactivity) as well as impaired detrusor contractility (Sakakibara, Fowler, & Hattori, 1999). White matter lesions (leukoaraiosis) demonstrated on MRI are significantly associated with neurogenic detrusor overactivity, and the authors suggest that urinary dysfunction might be an early sign of this condition (Sakakibara, Hattori, Uchiyama, & Yamanishi, 1999). Recent changes to standardized terminology of lower urinary tract function relating to detrusor overactivity recognize the frequent relation to neurological conditions such as stroke, referring to this as neurogenic detrusor overactivity (Abrams et al., 2002). Urge incontinence in older females has been associated with increased risk of falls and non-traumatic fractures (Brown et al., 2000).

Age-related changes in the urinary tract are difficult to discern from those of disease pathophysiology. Few longitudinal studies of healthy older people have been published, so age norms have not been agreed upon. Although a number of animal studies have suggested some cellular and neuronal changes, these findings are not readily

transferable to humans. Current thought suggests that cellular and tissue level aging includes smooth muscle degeneration and deposition of increased connective tissue (Naeem, L., & Morley, 2000), in addition to axonal degeneration and possible alterations to cholinergic (decreased muscarinic receptors) and adrenergic responses. These anatomical and neurological alterations result in functional changes in the lower urinary tract (Table 2-1) but do not of themselves cause urinary incontinence.

Although the age-related changes do not cause urinary incontinence, they may predispose the elderly patient to:

- urge urinary incontinence—the involuntary leakage of urine associated with a strong urge to void;
- stress urinary incontinence – leakage with increased abdominal pressure; or
- overflow incontinence – leakage associated with urinary retention.

Nocturnal urinary output also appears to change with age, with higher rates of urine excretion at night in older subjects. These changes are probably related to variation in arginine vasopressin (AVP) and atrial natriuretic hormone as well as a decline in renal sodium conserving mechanisms, impaired tubular sodium, and water reabsorption (Miller, 2000). Much of the research examining this phenomenon has involved frail hospital patients and nursing home residents, so whether variation in AVP level is a norm of aging or potentially a result of other disease processes is still subject to debate.

Finally, functional limitations may contribute to incontinence in at-risk patients. For example, mobility changes or pain from musculoskeletal disease, such as arthritis or osteoporotic spinal compression fractures, can make toileting and maintenance of

continence difficult. Persons with an Alzheimers dementia develop agnosia and apraxia, leading to difficulties in carrying out activities of daily living. These limitations, produced as effects of comorbid diseases, need to be considered in the assessment of the diabetic person with bladder dysfunction.

Effects of Diabetes on the Urinary Tract

The most likely cause of incontinence in the patient with DC is overflow incontinence, although the presenting symptoms might suggest stress or urge urinary incontinence. Patients with DC are also at increased risk of detrusor overactivity but whether this is due to DC alone or cerebral perfusion issues associated with hypercholesteremia, transient ischemic attacks, or stroke is not clear.

The classic triad of bladder symptoms associated with diabetic cystopathy include decreased bladder sensation, increased bladder capacity and impaired detrusor contractility with resultant increased post void residual (PVR) urine. Increased PVR leaves the individual prone to urinary tract infections, a common cause of acute confusion and functional decline in older adults. A possible link between deterioration of renal function and chronic asymptomatic bacteriuria in individuals with diabetes has been postulated (Geerlings et al., 2001). Neuropathies in diabetics have been extensively studied in recent years (Diabetes Control and Complications Trial Research Group, 1993; Dyck, Davies, Litchy, & O'Brien, 1997; Nathan et al., 2005), but none of these large trials included outcome measures relating to bladder dysfunction.

Increasingly, DC is described as a manifestation of autonomic neuropathy (American Diabetes Association, 2006; Boulton et al., 2005; Ueda et al., 1997; Walter, 1996), although some feel it may also represent peripheral somatic neuropathy (Mitsui et

al., 1999). Several classification systems for diabetic neuropathy have been suggested but none have included specific lower urinary tract function. Greene, Stevens, and Feldman (1999) proposed that genitourinary neuropathy fits within the autonomic neuropathy category along with sudomotor, cardiovascular and gastrointestinal neuropathies (Table 2-2 summarizes these). Autonomic neuropathies are felt to be serious and irreversible complications of diabetes.

Autonomic neuropathies in diabetes result in axonal degeneration, demyelination and fiber loss. Hyperglycemia has been implicated as a primary contributor to development of neuropathic complications. Tight control of blood glucose decreases long term neurological and microvascular complications of diabetes (Diabetes Control and Complications Trial Research Group, 1993), but the precise relationship of glycemic control and duration of diabetes to DC is not known. One possible mechanism of glucotoxicity in nervous tissue is increased polyol pathway activity in which accumulations of sorbitol and fructose induce damage (Mooradian & Thurman, 1999; Vinik, 1999). It has even been suggested that blood glucose concentration affects the rate at which aging occurs and that diabetes may be a syndrome of premature aging (Vinik, 1999). Other possible contributors to diabetic nerve damage include immune mechanisms, microvascular insufficiency, deficiency of growth factor and decreased expression of laminin, a glycoprotein important in nerve regeneration (Mitsui et al., 1999). To date, the likelihood of a multifocal etiology in diabetic autonomic neuropathy is recognized, but the exact mechanism of damage is not yet elucidated (Boulton et al., 2005).

Assessment of the Individual with Bladder Dysfunction

Assessment of the older diabetic individual with symptoms of bladder dysfunction includes identification of age-related changes and risk factors arising from physiologic, psychosocial and environmental influences.

History and Symptom Assessment

A description of the symptoms as experienced by the older adult or perceived by the caregiver is an important first step. Because DC is often insidious (Frimodt-Moller, 1980; Sasaki, Yoshimura, & Chancellor, 2003), the onset may be difficult to describe precisely. The classic symptoms of overflow incontinence or reduced contractility bladder with which the person with diabetes may present are weak stream, hesitancy in starting urination, dribbling (if high residual and resultant overflow incontinence is present), a sensation of incomplete emptying, leaking with increased abdominal pressure, and infrequent voiding (Ellenberg, 1980; Ziegler, 2001). However, some may present with both obstructive (voiding) as well as irritative (storage) symptoms (Ishigooka et al., 1996), others with recurrent asymptomatic bacturemia or symptomatic urinary tract infection (Nicolle, 2003) or even acute retention (Olapade-Olaopa, Morley, Carter, & Walmsley, 1997) . As a part of symptom management assessment (Larson et al., 1999), strategies the person uses to manage their symptoms, information about management of diabetes, and perception of glycemic control should be included. Past medical and surgical history and general systems review provide information on the comorbid conditions which could affect bladder function or produce functional limitations.

Physical Examination

Physical examination includes complete neurological evaluation with assessment of anal sphincter tone and saddle anesthesia. Examination of the rectum assesses stool presence and consistency, and, in males, prostatic size and shape; in females a gynecologic exam assesses pelvic organ prolapse and pelvic floor muscle tone as well as estrogenization of the vaginal tissue (Nitti, 1999) and the presence of *candida albicans* to which diabetic women are prone.

As DC is a manifestation of autonomic neuropathy (Boulton et al., 2005; Greene et al., 1999; Vinik & Mehrabyan, 2004), we suggest that screening for other signs of autonomic dysfunction should be included in the assessment of the older person with diabetes. In particular, heart rate variability and orthostatic hypotension (measured by blood pressure lying and standing), as these are risk factors in falls among seniors. It is not clear whether cardiovascular autonomic neuropathy occurs with or progresses at the same rate as DC, but the presence of cardiovascular dysautonomia may identify other problems that need to be addressed with the client.

Laboratory and Other Investigations

Microscopic urinalysis (and urine culture if indicated), creatinine, blood urea nitrogen (BUN) and periodic urine microalbumin to assess renal function are part of initial assessment. Serum glucose, and glycosalated hemoglobin (HbA_{1C}), which reflects 2-3 months of glycemic control, should also be obtained.

Because one of the hallmarks of DC is an increase in residual urine, the post void residual urine (PVR) should be monitored (Sasaki et al., 2003), either by portable ultrasound or in and out catheterization. Ideally, PVR should be measured within minutes

of voiding. Norms for acceptable level of PVR have not been established. A suggested acceptable range for older adults is 100-200 ml (Wagg & Malone-Lee, 1998).

A bladder diary (Table 2-3) should also part of the initial investigation of voiding function (Staskin et al., 2005), and assists in evaluating the amount and type of fluid ingested as well as voiding patterns. Most older patients have no difficulty completing a bladder diary.

Detailed assessment of bladder function with urodynamic studies is indicated if initial management is not successful or in patients whose symptoms are mixed, such as urgency or stress incontinence (Table 2-4). Urodynamic findings common to DC include impaired sensation, increased bladder capacity, reduced or absent detrusor contractility, inability to initiate voiding, and an increased PVR (Goldman & Appell, 1999). Detrusor overactivity with reduced contractility, linked to cerebral lesions for which diabetics are at increased risk, may also be diagnosed. As client-reported symptoms do not always match actual quantified function (Ishigooka et al., 1996), information from urodynamics can assist in developing an appropriate plan of management, including medications (Table 2-5).

Psychosocial and Cognitive Assessment

Since older diabetics are at risk for stroke and impaired cognition, the assessment should include baseline mental status (Kane, Ouslander, & Abrass, 2004), including completion of a standardized screening tool such as the Mini-Mental State Examination (Folstein, Folstein, & McHugh, 1973). Obtaining a cognitive history from a family member or caregiver helps determine whether impaired cognition is an issue. Functional and cognitive information should include activities of daily living and inquiries about

difficulties with memory, language, agnosia, apraxia, and behavioral changes (Kane et al., 2004).

Interventions

Little research has been published to guide practice in DC management. Evidence is modest at best for all interventions except glycemic control. Prevention of further diabetes-associated neuropathy is an important goal to modify or eliminate risk factors. Other goals of management of DC include the relief of symptoms, prevention of infection, maintenance of renal function, continence, and adequate bladder emptying (Goldman & Appell, 1999). A summary of strategies for DC management is provided in Table 2-6.

Glycemic Control

Hyperglycemia has been linked to neuropathy and other complications of diabetes (Diabetes Control and Complications Trial Research Group, 1993). Strategies to achieve optimal glycemic control include diet (including increased fiber), exercise and weight loss. Individuals with diabetes should be referred to a diabetes self-management teaching program for education on glycemic control. Age should not be a barrier to making an education referral. If cognitive impairment is an issue, it is essential that the caregiver also participates in the education.

Glycemic targets for preprandial self monitored blood glucose levels are 80-120 mg/dl (4.4-6.7 mmol/l). The target for glycated hemoglobin level (HbA_{1c}) is less than 7.0% (American Diabetes Association, 2006) and should be monitored routinely as part of follow-up. These targets may be modified upwards for some older individuals, especially if they are prone to hypoglycemic episodes. Individuals who are not able to

attain this target by diet and exercise alone will require oral glucose lowering agents and/or insulin.

Other preventative measures include control of hypertension and hyperlipidemia, as well as smoking cessation. ACE (angiotension converting enzyme) inhibitors are frequently used in diabetes for both blood pressure control and treatment of atherosclerotic renal vascular disease (Carr, 2001) . The target blood pressure for individuals with diabetes is less than 130/80 mmHg (American Diabetes Association, 2006).

Scheduled Toileting and Double Voiding

Advising patients to void two to four hourly during the day (timed voiding) (Frimodt-Moller, 1978b; Frimodt-Moller & Mortensen, 1980; Sasaki et al., 2003; Ziegler, 2001) and double voiding (Frimodt-Moller & Mortensen, 1980; Ziegler, 2001) may improve bladder emptying, improve continence, and minimize risk of infection. Double voiding involves attempting to empty the bladder by staying on the toilet and trying to void more than once with each trip to the toilet. As DC is gradual in onset, it may be useful to encourage the diabetic client to begin these habits even if the PVR is below 150 ml., or if they are asymptomatic or showing only moderate signs of cystopathy (Sasaki et al., 2003). Those with cognitive impairment might need supportive cueing from caregivers to carry out these strategies. These non-invasive strategies are worth trying, although there are no studies evaluating their effectiveness. We recommend that teaching of these strategies should be followed up with periodic measurement of PVR in patients with elevated residual urine to ensure that adequate bladder emptying is achieved.

Bladder Expression

Bladder expression, either by abdominal straining (Valsalva maneuver) or manual compression of the lower abdomen (Credé maneuver) has been studied in the spinal cord population, but not in the diabetic population. Wein (2002) very cautiously suggests this technique might be successful in those with an areflexic (hypotonic or atonic) bladder with some outlet denervation, presenting as stress incontinence. However, most experts agree that manual compression is contraindicated in conditions of increased vasal reflux, vesico-uretero-renal reflux, genitorectal prolapse and symptomatic urinary tract infection (Wyndaele et al., 2005), and should not be attempted unless urodynamic study has demonstrated that it is safe. This technique has largely been replaced with clean intermittent catheterization.

Intermittent Catheterization

Intermittent catheterization is one approach to achieve bladder emptying in DC when voiding strategies alone are ineffective, and has been identified as a strategy for those with diabetic cystopathy (Frimodt-Moller, 1978b; Frimodt-Moller & Mortensen, 1980; Kaplan & Blaivas, 1988; Sasaki et al., 2003; Ziegler, 2001). However, most of the research on intermittent catheterization has involved patients with spinal cord injury and children with myelomeningocele. There are no published studies of intermittent catheterization, and no evidence supporting the choice of either sterile or clean technique, in the diabetic population. If urethral irritation occurs, a single-use hydrophilic catheter is available which provides an evenly lubricated mucoid surface and can be more comfortable than a standard plastic catheter inserted with a water soluble lubricant (Cottenden et al., 2005; Vaidyanathan, Soni, Dundas, & Krishnan, 1994).

Few studies of intermittent catheterization in older people have been undertaken. Bennett and Diokno (1984) demonstrated that older adults were able to learn IC with careful education and support. However, many individuals may be uncomfortable with touching the urethra and older women are less likely to understand the anatomy of the female genitalia (Prashar, Simons, Bryant, Dowell, & Moore, 2000). Although case reports demonstrate that older women with diabetes have been successfully taught IC, reluctance to accept the strategy should be recognized.

The most appropriate frequency of performing intermittent catheterization is not known. The important concept is to maintain a low vesicle pressure so that there is no reflux to the kidneys and risk to renal function. Recommendations for catheterization vary from once, twice or four times daily to developing an individual routine by use of a bladder diary, noting the combined volume of voided and catheterized urine with a total volume of 400-500ml of voided and catheterized urine (Wagg & Malone-Lee, 1998).

Strategies to Manage Nocturnal Polyuria

Nocturnal polyuria arises from possible age-related changes but also from autonomic neuropathy in diabetics (Miller, 2000). Although eliminating nocturnal polyuria may not be realistic, the impact may be minimized by taking in most of the fluid for the day in the morning or early afternoon, avoiding caffeinated beverages in the evening, and ensuring the bladder is empty prior to going to bed. Placing a commode by the bedside at night may reduce risk of falls and fractures (Brown et al., 2000).

Pharmacologic Strategies

Currently there are no effective medications to assist with bladder emptying in DC. Bethanechol, a parasympathomimetic agent, has been used to treat urinary retention,

but results have been inconsistent (Bowers et al., 1987; Eftaiha, Amshel, & Shonberg, 1980; Vinik, 1999). A recent international review concluded that bethanechol and other parasympathomimetics do not have any beneficial effect for the treatment of overflow incontinence (Andersson et al., 2005). Intranasal DDAVP has been used to reduce nocturnal polyuria, but the safety of this agent in older persons, particularly around the risk of hyponatremia (Fonda et al., 2005), may limit its usefulness. Alpha blockers, may be helpful in outlet obstruction due to prostatic enlargement (Nickel et al., 2005). Research on agents such as beraprost, a prostacylin agent to enhance blood flow and cilostazol, a phosphodiesterase inhibitor, may prove useful in the future treatment of diabetic neuropathies (Vinik & Mehrabyan, 2004), although they are not yet available for clinical use.

Research Opportunities

With the paucity of research on effective interventions for DC, research based guidelines cannot yet be delineated. Nurses play a key role in assisting older adult clients in identifying and implementing interventions that result in positive functional consequences of diabetes and its chronic complications. Opportunities exist for nursing research to fill the gap in knowledge relating to older diabetics and the efficacy of voiding interventions such as scheduled toileting, infection rates of clean versus sterile intermittent catheterization and acceptability of intermittent catheterization as a method of management to older individuals and their caregivers. The efficacy of safety measures such as a commode at bedside during the night should be investigated. Evidence based care protocols have the potential to assist older persons with DC to minimize risk and remain as independent in their management of this chronic condition as possible.

Table 2-1

Changes in Lower Urinary Tract Function with Aging

- Decreased detrusor contractility
- Decreased bladder capacity
- Increased post void residual
- Decreased ability to delay voiding
- Decreased sensation of filling
- Decreased urinary flow rates
- Decline in the maximal urethral closure pressure and length (females)
- Increased prevalence in bladder outlet obstruction in males related to prostatic enlargement (males)

Table 2-2

Diabetic Neuropathies

Generalized (diffuse) neuropathies	Focal neuropathies (mono or multi focal)
➢ Sensorimotor neuropathies (acute and chronic) ➢ Autonomic neuropathies Sudomotor Cardiovascular Gastrointestinal Genitourinary	➢ Cranial neuropathy ➢ Nerve entrapment (e.g. from spinal stenosis) ➢ Lower limb/focal limb neuropathy ➢ Proximal motor (muscle wasting or amyotrophy) ➢ Chronic inflammatory demyelinating polyneuropathy

Adapted (Boulton et al., 2005; Greene et al., 1999).

Table 2-3

Example Bladder Diary

Date:					
Time	Amount/ type of drink	Urination (in toilet)	Incontinent episode (small or large)	Activity (e.g. coughing, getting up)	Bowel movement
6-7 am					
7-8 am					
8-9am					
9-10 am					
10-11 am					
11-12 am					
12-1 pm					
1-2 pm					
2-3 pm					
3-4 pm					
4-5 pm					
5-6 pm					
6-7 pm					
7-8 pm					
8-9 pm					
9-10 pm					
10-11 pm					
11pm- 6 am					

Table 2-4

Lower Urinary Tract Symptoms and Management Strategies

Symptom	Condition/ Possible Urodynamic Findings	Etiology	Management Strategies
Urge Urinary Incontinence (Over Active Bladder)	Involuntary leakage with or immediately preceded by urgency Urodynamics: Detrusor overactivity (involuntary detrusor contraction), inability to inhibit detrusor contraction, low capacity	Idiopathic, neurogenic, urinary tract infection, bladder cancer, outlet obstruction	Bladder training, timed toileting Fluid and constipation management Medication review Pelvic muscle exercises +/- biofeedback Estrogen Anticholinergic/antimuscarinic agents Incontinence pads Environment modifications (e.g. bedside commode) Sacral nerve neuromodulation, augmentation cystoplasty, urinary diversion (rare)

Symptom	Condition/ Possible Urodynamic Findings	Etiology	Management Strategies
Stress Urinary Incontinence	Involuntary leakage on effort, exertion, sneezing or coughing Urodynamics: incompetent urethral closure mechanism and/or leakage during increased abdominal pressure in the absence of a detrusor contraction	Pelvic floor prolapse, prior urethral bladder or pelvic surgery, neurogenic	Weight loss Fluid increase or decrease Smoking cessation Constipation management Pelvic muscle exercises +/- biofeedback Pessary Incontinence pads Alpha agnonists Pubovaginal sling Periurethral bulking agents
Mixed Incontinence (Urge and Stress)	Involuntary leakage associated with urgency as well as exertion, effort, sneezing or coughing		Combination of above Initial focus is on the dominant symptom

Symptom	Condition/ Possible Urodynamic Findings	Etiology	Management Strategies
Overflow	Retention of urine with incontinence (associated with chronic urinary retention from poorly contractile bladder or/& outlet obstruction). May have reduced or absent bladder sensation, slow or intermittent stream, hesitancy, straining, a feeling of incomplete emptying, &/or dribble post micturation Urodynamics: Diminished sensation	Poorly contractile bladder due to neurogenic causes (diabetes, PD, MS, spinal compression from cauda equina or metastatic cancer, dyssynergia Outlet obstruction from benign prostatic	Referral to urologist or urogynecologist Relief of obstruction if present Clean intermittent catheterization Medication review Alpha blockers Indwelling catheter (last resort)

Symptom	Condition/ Possible Urodynamic Findings	Etiology	Management Strategies
	during filling cystometry; increased capacity; detrusor underactivity; inability to initiate flow; reduced flow with increased detrusor pressure (obstruction); increased PVR	hypertrophy, prostatic or bladder cancer, cystocele, constipation, forgotten pessary	

Table 2-5

Medications commonly prescribed for the treatment of urinary incontinence

Classification *examples*	Mechanism of Action	Dose	Side Effects	Contraindications
Drugs for over active bladder syndrome (detrusor overactivity, urge urinary incontinence)				
Anticholinergics/ Antimuscarinics *oxybutynin* *oxybutynin XL*	Antispasmodic and slight analgesic effect on smooth muscle; inhibits acetylcholine in smooth muscle Metabolized primarily by the liver	2.5-5 mg daily to qid XL available in 5 and 10 mg	Constipation, dry mucosa (mouth, vagina, eyes); in older adults may cause confusion, impaired cognition; blurred vision; urinary retention (monitor PVR) Caution: gradually increase dose, low doses effective in some older patients	Anticholinergic medications contraindicated in narrow angle glaucoma, GI obstruction or atony, myasthenia gravis, urinary retention or increased PVR (can use with intermittent

Classification *examples*	Mechanism of Action	Dose	Side Effects	Contraindications
				catheterization
tolterodone *tolterodone LA*	More selective on muscarinic (M3) receptors than oxybutynin resulting in fewer side effects	1-2 mg, may take up to 8 weeks to reach effective level	Explain that LA capsule will be excreted in feces. As above, but less pronounced due to selectivity of M3 bladder receptors over salivary receptors	As above; adjust dosage if concurrent use of CYP-450 3A4 inhibitors (fluxetine ups concentration 4.8 times)
propantheline bromide	Non-selective anticholinergic and antispasmodic	15-30 mg q6h	As for oxybutynin	As for oxybutynin
Tricyclic Antidepressants *imipramine*	Serotonin and norepinephrine reuptake inhibitors. Also has anticholinergic properties.	25 mg qhs, up to 25 mg tid	As above. Orthostatic hypotension an issue in older adults, increasing risk for falls Monitor BP lying and standing	Side effects are common. Not a drug of choice in older adults

Classification *examples*	Mechanism of Action	Dose	Side Effects	Contraindications
Drugs to increase urethral sphincter tone (for stress UI)				
Alpha Adrenergic Agents *pseudoephedrine*	Stimulates alpha fibers at bladder neck and sphincter causing increased tone	75 mg q12h	Hypertension, insomnia, tremor, agitation	Hypertension, narrow angle glaucoma; those on MAO inhibitors. Caution in older adults.
Hormone Based Therapies *Estrogen cream* *Slow release estradial ring*	Reduces irritation from atrophic vaginitis (do not provide systemic effects due to low dose)	Cream: 1-2 gm qhs x 2 weeks then 2x per week at hs Change ring q 3 months	May cause sore breasts, spotting. Apply intravaginally, not on labia	Endometrial, ovarian or breast cancer.

Classification *examples*	Mechanism of Action	Dose	Side Effects	Contraindications
Drugs which decrease urethral sphincter tone (obstruction due to benign prostatic hypertrophy				
Alpha Adrenergic Antagonists *terazosin* *prazosin* *doxazopin*	Block alpha 1A fibers at the bladder neck and sphincter causing decreased tone and improving voiding in males with mild obstruction	Start with low dose, increase slowly to therapeutic effect	Postural hypotension, syncope, fainting. Increased risk of falls – monitor BP lying and standing.	Those on antihypertensive treatment may need titration of dose.
5-alpha Reductase Inhibitors *finasteride*	Inhibits conversion of testosterone to dihydrotestostereone causing a reduction in prostate size and improving voiding symptoms	5 mg daily	Taken long term. The prostate will begin to enlarge again when it is stopped.	Food may delay rate and extent of oral absorption. Requires close monitoring in urinary obstruction.

Classification *examples*	Mechanism of Action	Dose	Side Effects	Contraindications
Drugs which increase the activity of the detrusor muscle (detrusor underactivity)				
Cholinomimetics (muscarinic antagonists) *bethanechol*	Activate muscarinic receptors triggering detrusor contraction, and relaxing the bladder trigone and sphincter	10-25 mg po daily 5 mg sc for acute retention	Clinically has not been shown to be consistently effective. Nausea, vomiting, sweating, blurred vision, bradycardia, intestinal colic.	Obstruction of the bladder outlet. May aggravate respiratory conditions such as asthma.
Cholinesterase inhibitors *neostigmine*	Indirectly act as cholinomimetic by inhibiting acetylcholinesterase and increasing the concentration of acetylcholine at neuromuscular receptor sites.	15 mg po 0.5-1 mg sc for acute retention	As above, plus restlessness	As above

Table 2-6

Summary of Management Strategies for Diabetic Cystopathy

Strategy	Comments
Glycemic Control	Includes diet, exercise, weight loss Oral glucose lowering agents Insulin Stimulators (Secretagogues) • Sulfonylureas (e.g. glyburide, gliclazide) • Meglitinides (e.g. repaglinide) Insulin Sensitizers • Biguanides (e.g. metformin) • Thiazolidinediones (e.g. rosiglitazone, pioglitazone) Other • Alpha glucosidase inhibitors (e.g. acarbose) Insulin
Voiding strategies • Scheduled toileting • Double voiding • Bladder expression	First line strategies – follow up PVR measurement needed to assess bladder emptying Limited use - only if urodynamics demonstrates no vesicoureteral reflux

Strategy	Comments
Catheterization • Intermittent catheterization • Indwelling catheter	If voiding strategies ineffective Last resort
Nocturnal polyuria • Fluid management • Avoid caffeinated beverages in the evening • Empty bladder prior to going to bed	Instruct client to take most of fluids during the day

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CHAPTER 3

Paper 2: Conservative Management of Postprostatectomy Urinary Incontinence[1]

Footnote:

[1]A version of this chapter has been published and revision accepted for publication

Hunter, K. F., Cody, J., Glazener, C. & Moore, K. N. (2004) Conservative management of post prostatectomy urinary incontinence. (Cochrane Review). In: *The Cochrane Library*, Issue 3, 2004. Chichester, UK: John Wiley & Sons UK

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Conservative Management of Postprostatectomy Urinary Incontinence

It is not uncommon for men to have incontinence (UI) after prostatectomy. The reported frequency varies depending on the type of surgery and surgical technique (2001; Peyromaure, Ravery, & Boccon-Gibod, 2002), the definition and quantification of incontinence (Grise & Thurman, 2001; Peyromaure et al., 2002), the timing of the evaluation relative to the surgery, and who evaluates the presence or absence of incontinence (physician or patient) (Donnellan, Duncan, MacGregor, & Russell, 1997; McCammon, Kolm, Main, & Schellhammer, 1999). Reported prevalence rates of UI after radical prostastectomy (RP) for prostate cancer vary from 5% to over 60% (Hunskaar et al., 2002).For example, in one study at 3 months after RP (Donnellan et al., 1997), 51% were subjectively wet (self-report) but 36% were wet on pad testing (objective). By 12 months, 20% were subjectively still wet, but only 16% were classed as wet using objective criteria. After transurethral resection of the prostate (TURP) for benign prostate disease, UI is less common at three months after operation (e.g. 10% needing to wear pads), but longer term data are not available (Emberton et al., 1996).

After both types of operation, the problem tends to improve with time; it declines and plateaus within one to two years postoperatively (Hunskaar et al., 2002). The most beneficial time for conservative interventions is not yet understood. However, some men are left with incontinence that persists for years afterwards and which has a profoundly negative effect on quality of life. Although conservative management may be associated with low morbidity, there is considerable investment in time, effort and expertise insofar as the health providers are concerned, as well as time, effort and expectations on the part

of the affected patients so that evidence on the effectiveness of these interventions must be clearly established.

Continence Mechanisms

Urinary continence depends on a complex interaction of smooth and striated muscle fibres blended together to form the continence mechanism. Considerable debate has existed in the literature as to whether incontinence after prostatectomy is due to an effect on the detrusor (bladder) muscle or on the sphincter, as commonly these abnormalities coexist (Peyromaure et al., 2002). New detrusor overactivity and intrinsic sphincter deficiency due to sphincteric injury (Ficazzola & Nitti, 1998; Groutz, Blaivas, Chaikin, Weiss, & Verhaaren, 2000; McGuire, 1990) or weakness (Majoros, Bach, Keszthelyi, Hamvas, & Romics, 2006) are cited as the most important causes of persistent incontinence after RP. Debate continues on whether detrusor overactivity (Goluboff, Chang, Olsson, & Kaplan, 1995; Leach, 1995) is a primary or secondary factor. Whereas some report overactivity as the primary cause of postprostatectomy incontinence (Goluboff et al., 1995; Leach, 1995), others argue strongly that even if other factors play a role, sphincter deficiency is the primary cause of UI after RP (Aboseif, O'Connell, Usui, & McGuire, 1996; Chao & Mayo, 1995; Gudziak, McGuire, & Gormley, 1996; Kondo, Lin, Nordling, Siroky, & Tammela, 2002; Majoros et al., 2006; Winters, Appell, & Rackley, 1998).

Risk factors for postprostatectomy UI after RP include pre-existing abnormalities of detrusor contractility (Leach, 1995) and older age (Diokno, 1997; Kondo et al., 2002), possibly due to progressive reduction in sphincter striated muscle cells with age (Strasser, Steinlechner, & Bartsch, 1997). Other risk factors include previous TURP (Kondo et al.,

2002); pre-operative radiotherapy (Kondo et al., 2002; Rainwater & Zincke, 1988); trauma; spinal cord lesion; new obstruction due to recurrence, bladder neck contracture, or urethral stricture (Litwiller, McIntire, Schnitzer, & Roehrborn, 1997); Parkinson's disease (Kondo et al., 2002; Staskin, Vardi, & Siroky, 1988); dementia; and medications (Khan, Mieza, Starer, & Singh, 1991; Yalla et al., 1982). A surgeon's inadequate skill and expertise (Eastham et al., 1996) and having surgery in a hospital which performs fewer than 20 radical prostatectomies a year (Albertsen, Lu-Yao, & Warren, 1997) have also been implicated.

After TURP, UI is thought to most likely to be due to pre-existing abnormalities of bladder function such as poor compliance or detrusor overactivity, rather than direct sphincter injury (Abrams, 1991), possibly because removal of the prostatic tissue removed some of the protective mechanism for continence.

The treatments recommended for postprostatectomy UI are usually 'conservative,' not involving drugs or surgery. Six categories of conservative management are considered in this review, singly and in combination when appropriate.

1. Pelvic floor muscle training (PFMT)

This involves any method of training the pelvic floor muscles to contract, including teaching performance of an accurate voluntary pelvic floor muscle contraction, and coordinating and timing the contraction against increases in intra-abdominal pressure, often called functional PFMT.

The theoretical basis of PFMT is that repeated, volitional contractions of selected pelvic floor muscles may improve their strength and efficiency during periods of increased intra-abdominal pressure. In a systematic review of the literature on female UI,

Berghmans and colleagues noted that a pelvic floor muscle contraction may raise the urethra and press it towards the symphysis pubis, prevent urethral descent, and improve structural support of the pelvic organs (Berghmans et al., 1998). They further pointed out that PFMT may result in hypertrophy of the periurethral striated muscles thereby increasing the 'external mechanical pressure on the urethra'.

2. Biofeedback

Traditionally, biofeedback involves the use of equipment to provide visual or auditory feedback about the pelvic floor muscle contraction to enable one to train, strengthen and increase endurance and coordination of the pelvic floor muscles contractions. Simple auditory biofeedback can also be provided by the therapist informing the patient when a contraction is felt through digital anal examination during the pelvic floor muscle contraction.

3. Electrical stimulation (non-invasive) delivered via surface electrodes.

Anal electrical stimulation. Any type of electrical stimulation using a non-invasive surface anal probe designed for the therapy. The intention of electrical stimulation is to facilitate contraction of the periurethral striated muscle.

Sticky patch electrodes, also called transcutaneous electrical nerve stimulation (TENS). Transcutaneous electrical nerve stimulation is a low intensity, sensory nerve stimulation used for detrusor overactivity, delivered at various sites, using patch electrodes. Sites include the sacral dermatomes (Hasan, Robson, Pridie, & Neal, 2005), dorsal penile nerve (Nakamura & Sakurai, 1984), hamstring and quadriceps muscle (Okada, Igawa, Ogawa, & Nishizawa, 1998), and the posterior tibial or perineal nerves (McGuire, Zhang, Horwinski, & Lytton, 1983).

4. Lifestyle adjustment

This includes fluid adjustment, diet, caffeine elimination, physical exercise, weight loss and cessation of smoking.

5. Extra-corporeal magnetic innervation

This involves the use of a magnetic chair to stimulate contraction of the pelvic floor muscles (Galloway et al., 2000).

6. External penile compression devices

These devices use an external clamp to achieve non-surgical compression of the urethra.

The initial review on the topic of postprostatectomy urinary UI, first published in 1999 (Moore, Cody, & Glazener, 1999a) and updated in 2001 (Moore, Cody, & Glazener, 2001), only considered post operative PFMT, biofeedback and electrical stimulation. In the last update (Hunter, Moore, Cody, & Glazener, 2004), the review was broadened to include studies evaluating lifestyle adjustment, external penile compression devices and extracorporeal magnetic innervation. The current update includes studies on men after TURP as well as pre operative PFMT.

Objectives

The objective in undertaking the review was to determine the effectiveness of conservative management for urinary UI after transurethral, suprapubic, laparoscopic, radical retropubic or perineal prostatectomy, including any single conservative therapy or any combination of conservative therapies. Pharmacological agents will be considered in separate reviews. The use of the term 'sham therapy' in this review means any therapy that could not influence the pelvic floor muscles such as placing an electrical stimulation probe in the anus but not turning it on.

The following comparisons were made for men having treatment of UI after prostatectomy:

Transurethral Resection of the Prostate (TURP)

1. Post-operative TURP PFMT versus no treatment or placebo or sham therapy.

2. Post-operative TURP PFMT plus biofeedback versus PFMT alone.

Radical prostatectomy (RP)

3. Post-operative RP PFMT versus no treatment or placebo or sham therapy

4. Anal electrical stimulation versus no treatment or placebo or sham therapy

5. Transcutaneous electrical nerve stimulation (TENS) versus no treatment or placebo or sham therapy

Biofeedback

6. Preoperative RP PFMT plus biofeedback versus no therapy or sham therapy

7. Pre and post operative RP PFMT plus biofeedback versus no therapy or sham therapy

8. Post-operative RP PFMT plus biofeedback versus no therapy or sham therapy

9. Post-operative RP PFMT plus biofeedback versus PFMT alone

Anal / perineal electrical stimulation

10. Post-operative RP PFMT plus anal electrical stimulation versus no treatment or placebo or sham therapy

11. Post-operative RP PFMT plus anal electrical stimulation versus PFMT alone

12. Post-operative RP PFMT plus perineal electrical stimulation versus PFMT alone

13. Post-operative RP PFMT plus anal electrical stimulation plus biofeedback versus no treatment or placebo or sham therapy

14. Post-operative RP PFMT plus anal electrical stimulation plus biofeedback versus

PFMT alone

15. Post-operative RP anal electrical stimulation versus perineal electrical stimulation

Other comparisons

16. PFMT plus transcutaneous electrical nerve stimulation versus PFMT alone

17. PFMT versus transcutaneous electrical nerve stimulation alone or biofeedback alone or anal electrical stimulation alone or no treatment

18. Lifestyle adjustment versus no therapy or sham therapy

19. Extracorporeal magnetic innervation versus no therapy or sham therapy

20. External penile compression devices (penile clamp) versus no therapy or sham therapy.

We have not listed all possible comparisons here. As and when new trials address new comparisons, these will be added to the review.

Criteria for Considering Studies for this Review

Types of Studies

Randomised or quasi-randomised controlled trials of conservative management of urinary UI after TURP or RP were sought.

Types of Participants

Men with urinary incontinence who had undergone or continent men booked for a prostatectomy for either benign prostatic hyperplasia or prostate cancer. Studies involving men experiencing urinary UI prior to prostatectomy were excluded.

Types of Interventions

PFMT, biofeedback, electrical stimulation via a surface electrode (anal probe electrical stimulation or sticky patch electrode transcutaneous electrical nerve stimulation (TENS)),

extra-corporeal magnetic innervation, lifestyle adjustment, and external penile compression device compared with no treatment or with each other, alone or in combination.

Types of Outcome Measures

Primary outcomes:

1. Patient reported symptoms

Self report of UI (number not cured or improved)

Number of pad/clothing changes (pad changes per 24 hours)

Frequency of UI from self-report or diary (incontinent episodes per 24 hours)

Frequency of micturitions per 24 hours

De novo urge symptoms

2. Objective Measures

Standardised pad test (24 hour or 1 hour) measuring grams of urine lost

Secondary outcomes:

1. Patient satisfaction

Self report of satisfaction with treatment

2. Health status measures

Impact of UI e.g. Incontinence Impact Questionnaire (Uebersax, Wyman, Shumaker, McClish, & Fantl, 1995)

General health status e.g. Short Form 36 (Ware, 1993)

Quality of life e.g. European Organisation for Research and Treatment of Cancer (EORTC QLQ-C30), version 2 (Aaronson et al., 1993; Aaronson, Bullinger, &

Ahmedzai, 1988)

Symptom inventory e.g. International Prostate Symptom Score (IPSS) (Barry et al., 1992)

3. Adverse events due to treatment

4. Health economics

Cost of intervention

Resource implications of differences in outcome

Economic analysis (cost effectiveness, cost utility)

5. Other outcomes

Non pre-specified outcomes judged important when performing the review.

Search Strategy for Identification of Studies

This review has drawn on the search strategy developed for the Incontinence Review Group. Relevant trials were identified from the Group's specialised register of controlled trials which is described, along with the group search strategy, under the Incontinence Group's details in *The Cochrane Library*. The register contains trials identified from MEDLINE, CINAHL, The Cochrane Central Register of Controlled Trials (CENTRAL) and hand searching of journals and conference proceedings. The Incontinence Group's trials register was searched using the Group's own keywording system, the search terms used were:

({design.cct*} OR {design.rct*})

AND

({topic.urine.incon.postprost*})

(All searches were of the keyword field of Reference Manager 9.5 N, ISI ResearchSoft).

Date of the most recent search of the register for this review: January 2006.

The trials in the Incontinence Group's specialised register are also contained in The Cochrane Central Register of Controlled Trials (CENTRAL).

For this review extra specific searches were performed by one of the reviewers. These are detailed below.

Systematic Searches of Electronic Bibliographic Databases

The following electronic bibliographic databases were searched (date search as performed: 10 January 2006):

MEDLINE - dates searched: January 1966 to January 2006;

EMBASE - dates searched: January 1988 to January 2006;

PsycLIT - dates searched: January 1984 to January 2006;

CINAHL - dates searched: January 1982 to January 2006;

ERIC - dates searched: January 1984 to January 2006.

The following search terms were used in each database (no limits were applied to the searches):

incontinence, urinary, male, postprostatectomy, stimulation, electrical stimulation, biofeedback, pelvic muscle exercises, Kegel exercises, behavioural, behaviour, behavior, therapy, behaviour modification, therapy, physiotherapy, lifestyle, weight loss, caffeine, smoking, extracorporeal magnetic innervation, external penile compression devices, continence, bladder control, quality of life, randomised (randomised) controlled trial, evaluation, effectiveness, efficacy, outcomes.

Handsearching of Conference Proceedings

The following conference proceedings were handsearched:

- American Urological Association (years searched: 1989-2005) Supplement to the Journal of Urology, published as a supplement.
- Society of Urologic Nurses and Associates (SUNA) (formerly American Urologic Association Allied) these abstracts are not published but are available in the SUNA office. Annual meeting (years searched: 1991 to 2003);1991-Las Vegas, NV; 1992-Washington, DC; 1993-San Antonio, TX; 1994-San Francisco, CA; 1995-Las Vegas,NV; 1996-Orlando, FL, 1997-New Orleans, LA. Biannual incontinence meeting (years searched: 1992 to 2001); 1992-Tampa, Fla (1st meeting), 1994-Phoenix, 1996-Dallas, 1998-Orlando, 2000-Nashville, 2004-Chicago, 2006-NYC; Understanding urodynamics seminar (years searched: 1993-1996); 1993-Denver, CO; 1994-San Antonio, TX; 1995-Cleveland, OH; 1996-St Louis, MO.
- Wound Ostomy and Continence Nurses (years searched: 1996, 1997,1999 to 2005). Annual meeting: 1996- Seattle, WA; 1997-Nashville, TN; Incontinence meeting (biannual); 1997-Beverly Hills (1st meeting); 1999-Austin, TX. (No further Incontinence meetings.)
- International Continence Society (years searched: 1980 to 2005). Published proceedings in Neurourology and Urodynamics.

The reference lists of relevant articles were searched for other possibly relevant trials. Investigators were contacted to ask for other possibly relevant trials, published or unpublished. No language or other limits were imposed on the searches.

Methods of the Review

The methodological quality of the identified trials was assessed using the Cochrane Incontinence Group's criteria presented in the *The Cochrane Library*. For the initial review and first update, this was performed by two reviewers (KM, DJC) with a consensus reached through discussion if there was any disagreement. The same two reviewers also independently performed data abstraction. Any discrepancies were discussed until agreement was reached.

For the second update, a similar approach was used. In this review, phase one resulted in an initial list of 26 titles (some with abstracts) generated for the review which were assessed by one reviewer (KH). Sources of the titles were as follows: Cochrane Incontinence group specialised register search (20), update search of MEDLINE, EMBASE, CINAHL, PsycLIT and ERIC databases by one author (KH) (4) and ICS proceedings (2) for a list of 26 potentially relevant articles and abstracts. This list was then reviewed independently by two reviewers (KH and KM) and results compared. The full text article of references or abstracts identified as potentially relevant by either reviewer were retrieved by one reviewer (KH) and reviewed by both. Reference lists of relevant review articles were reviewed to identify any further trials. References were assessed based on the population, interventions, control, outcomes and overall study design. From this, 10 potentially relevant trials for addition to the review were identified.

In phase two, using the full text of the potentially relevant published studies and abstracts, the same two reviewers (KH and KM) independently reviewed the studies for relevance and inclusion, based on the criteria described above. One author (KH) contacted five authors for further data and/or clarification of methods. Methodological

quality of eligible trials for the initial review and first update was assessed independently by two reviewers (Moore et al., 2001). For the second update, potentially relevant studies were assessed independently by two reviewers (KH, KM) and results compared. One reviewer (KH) not previously involved with the review also reassessed the quality of trials included in previous versions of the reviews. For the current update, two reviewers (KH, KM) independently assessed the potentially relevant studies and compared their results. As in the previous update, two approaches to quality assessment were used. The first was the quality assessment tool published in the Cochrane Incontinence Group module (Grant et al., 2003); the second was the scale developed by Jadad (1996). Disagreements were resolved through discussion; third party arbitration was not required.

The Cochrane Incontinence Group assessment tool is not scored. The following methodological parameters are included:

1) identification of study as randomised or quasi-randomised;

2) description of inclusion/exclusion criteria;

3) potential for selection bias (quality of random allocation concealment) rating;

4) potential for bias around time of treatment or during outcome assessment (blinding) rating;

5) potential for selection bias in analysis (description of withdrawals/dropouts/lost to follow up, analysis on intention to treat);

6) appropriate statistical analysis.

The second quality assessment was the Jadad scale (Jadad et al., 1996) which is scored in the following manner:

1) was the study described as randomised (this includes the use of words such as

randomly, random, and randomisation)? (yes = 1, no = 0);

2) was the study described as double blind? (yes = 1, no = 0);

3) was there a description of withdrawals and dropouts? (yes = 1, no = 0).

Add points:

Question 1) if randomisation method described and appropriate (1 point)

Question 2) if double blinding method described and appropriate (1 point)

Deduct points:

Question 1) if randomisation method described and inappropriate (1 point)

Question 2) if double blinding method described and inappropriate (1 point)

For the trials added to the 2004 and 2006 updates of the review, data were extracted independently by two reviewers (KH and KM) using a standard form developed for this update. The following information was included on the standard form that was developed:

- study method and characteristics (design, method of randomisation, inclusion/exclusion criteria, withdrawals/dropouts);
- participants (population, age);
- type of intervention, timing and duration of therapy, co interventions;
- control (no treatment or sham therapy);
- outcomes (types of outcome measures, reported outcomes, adverse events).

Extracted data were compared by two reviewers (KH and KM) for completeness and accuracy, and cross checked by the other reviewers (CG, DJC). Disagreements were resolved through discussion and review of the trial report. Data were entered into Review Manager software (RevMan 4.2.3) by KH and KM. The data were evaluated for

publication bias using graphical (i.e. funnel plot) evaluation only. This is discussed in the results section.

For dichotomous outcomes, data were summarized (e.g. number of people for whom an outcome is present or not) and relative risks (RR) calculated with their 95% CIs. For continuous outcomes, the number in each group was summarised and the mean value for each group calculated as weighted mean differences (WMD) if the same scale (e.g. pad test in grams of urine) was used for the outcome measurement. A fixed effect model was used to calculate the summary statistic and the 95% confidence intervals. Heterogeneity was assessed visually. Forest plots were examined and potential sources influencing heterogeneity identified. Possible sources of heterogeneity were explored statistically through subgroup analysis. Currently, the Cochrane Incontinence Group uses the Chi-squared test for heterogeneity and the I-squared statistic (Higgins, Thompson, Deeks, & Altman, 2003). Where synthesis was not appropriate, a narrative overview was planned.

Comparisons of the outcomes of the chosen interventions with no treatment, with each other, and in combination were planned *a priori* for the review update. Data were not available for all planned comparisons. As there was considerable diversity in the length of time interventions were carried out and in how this time was reported, the data were further divided into categories by length of time. In addition, in planning the update, subgroup analysis based on type of surgery (RP or TURP) was planned.

Attempts were made to contact authors of trial reports if clarification was necessary. Included trial data were processed as described in the Cochrane Collaboration Handbook (Clarke & Oxman, 2003). Studies were excluded from the review if they made

comparisons other than those pre-specified or if data were unavailable. Excluded studies are listed with reasons for their exclusion.

Results

Description of Studies

At the time of the previous update (Hunter et al., 2004), ten trials (Bales et al., 2000; Franke et al., 2000; Joseph & Chang, 2000; Mathewson-Chapman, 1997; Moore, Griffiths, & Hughton, 1999b; Moore et al., 2004; Opsomer, Castille, Abi Aad, & van Cangh, 1994; Parekh et al., 2003; Porru et al., 2001; Van Kampen et al., 2000) were included in the review. All involved patients who had undergone some form of RP. Four studies (Pulker, 2002; Salinas Casado et al., 1991; Salinas Casado et al., 1996; Zermann, Ishgooka, Wunderlich, Wilhelm, & Shubert, 1999) were excluded as they were descriptive studies of conservative interventions and did not include a control group for comparison. Of these, two were English language abstracts (Pulker, 2002; Zermann et al., 1999) while the other two (Salinas Casado et al., 1991; Salinas Casado et al., 1996) were Spanish with an English abstract. Another study (Chang et al., 1998) was excluded as it did not meet the criteria for random assignment to groups. A translation for one German language trial (Bocker & Smolenski, 2002) was obtained through the Cochrane Incontinence Group but the trial was not included as data for the postprostatectomy participants were not separated from a group of female participants who had recovered from polio. A trial (Bennett, Foote, Green, Killorin, & Martin, 1997) that had been included in the list of ongoing trials in the original review was excluded as it was only available in abstract and attempts to contact the author had been unsuccessful. Three additional trials identified in earlier versions of the review as ongoing (Ceresoli et al.,

2002; Griebling, Kreder, Sueppel, & See, 1999; Nehra et al., 2001) were excluded as they were in abstract form only with no data available, and attempts to contact the authors were unsuccessful.

Excluded and ongoing trials. For this update, in addition to the ten trials previously included in the analysis, ten potentially relevant studies on conservative management of postprostatectomy UI were identified from the literature. Five of these studies (Cornel, de Wit, & Witjes, 2005; Crevenna, Zoch, Keilani, Quittan, & Fialka-Moser, 2003; Ip, 2004; McGlynn et al., 2004; Seki et al., 2005) were excluded as they did not meet the criteria of the review. Three of these studies (Cornel et al., 2005; Crevenna et al., 2003; Seki et al., 2005) did not include control groups, one described an intervention not included in the study (Ip, 2004), and the last was a case report (McGlynn et al., 2004). An additional study did not have published data in a usable form (Yokoyama et al., 2004). The authors were contacted, but unfortunately no further data were available and the study was excluded.

One trial (Glazener et al., 2004) remains ongoing.

Included trials. Included in the review update at this time were seven additional trials (Burgio et al., 2006; Dubbelman, Groen, & Bosch, 2004; Filocamo et al., 2005; Floratos et al., 2002; Hoffmann, Liedke, Dombo, & Otto, 2005; Moore, Chetner, Valiquette, & Herbison, 2006; Wille, Sobottka, Heidenreich, & Hofmann, 2003), bringing the total number of included trials to seventeen. Four recently published studies (Burgio et al., 2006; Dubbelman et al., 2004; Filocamo et al., 2005; Hoffmann et al., 2005) met the criteria and were included in the review. One study previously listed as ongoing (Moore et al., 2006) was completed, and the authors provided data for inclusion

in the review. As well, further methodological and background data were obtained from the authors of two published studies (Floratos et al., 2002; Wille et al., 2003) previously excluded, which allowed us to include the studies in this update.

Types of populations. Fifteen trials involved 1581patients undergoing RP (Bales et al., 2000; Burgio et al., 2006; Dubbelman et al., 2004; Filocamo et al., 2005; Floratos et al., 2002; Franke et al., 2000; Hoffmann et al., 2005; Mathewson-Chapman, 1997; Moore et al., 2006; Moore et al., 1999b; Moore et al., 2004; Opsomer et al., 1994; Parekh et al., 2003; Van Kampen et al., 2000; Wille et al., 2003); one trial involved 58 patients after TURP (Porru et al., 2001); and one trial included one patient after TURP, the remaining 10 having RP (Joseph & Chang, 2000). In addition to the variation in surgical approach, different types of participants were recruited in some trials:

- preoperatively (Bales et al., 2000; Burgio et al., 2006; Moore et al., 2006; Parekh et al., 2003; Wille et al., 2003),
- within days or up to two weeks postoperatively or after catheter removal (Dubbelman et al., 2004; Filocamo et al., 2005; Floratos et al., 2002; Franke et al., 2000; Hoffmann et al., 2005; Mathewson-Chapman, 1997; Porru et al., 2001; Van Kampen et al., 2000), or
- weeks to months after surgery (Joseph & Chang, 2000; Moore et al., 1999b; Moore et al., 2004; Opsomer et al., 1994)

This variation may lead to different populations being studied in the trials: those experiencing early UI (many of whom are likely to recover continence spontaneously) and those with persistent UI. For this reason, the decision was made by the authors to separate pre-operative and post-operative studies in the analysis.

Types of interventions. In the included trials, there was considerable variation in the type and intensity of interventions. The duration of the treatment interventions varied from four weeks up to one year.

- Four trials examined PFMT alone in comparison to no treatment or sham (three in post RP patients (Dubbelman et al., 2004; Filocamo et al., 2005; Moore et al., 1999b), and one in post TURP patients (Porru et al., 2001)). Trials in which both intervention and control groups were exposed to standard pre-operative verbal or written information on pelvic muscle exercises followed by a specific PFMT protocol only in the intervention group were included in this grouping.
- Nine trials used PFMT with biofeedback as the intervention (Bales et al., 2000; Burgio et al., 2006; Floratos et al., 2002; Franke et al., 2000; Joseph & Chang, 2000; Mathewson-Chapman, 1997; Moore et al., 2006; Parekh et al., 2003; Van Kampen et al., 2000).
- Two trials had intervention groups that underwent PFMT with anal electrical stimulation (Moore et al., 1999b; Wille et al., 2003). Two other trials had intervention groups who had PFMT, anal electrical stimulation and biofeedback (Opsomer et al., 1994; Wille et al., 2003). Hoffman (2005) published a three arm trial involving groups assigned to PFMT alone, PFMT with anal electrical stimulation and PFMT with perineal electrical stimulation.
- One trial compared external penile compression devices as the intervention (Moore et al., 2004).

No trials testing lifestyle changes alone were identified for inclusion.

Types of outcome measures. There was lack of consistency in the reporting of outcome measures.

- In terms of the primary objective outcome of interest in this review, only five of the included trials (Joseph & Chang, 2000; Mathewson-Chapman, 1997; Moore et al., 2006; Moore et al., 1999b; Moore et al., 2004) reported results of a standardized pad test. Three other authors (Dubbelman et al., 2004; Franke et al., 2000; Opsomer et al., 1994) reported using a pad test, but data were not reported or were incomplete. One study (Hoffmann et al., 2005) reported results in terms of a provocative 1 hour pad test. Floratos (2002) also used a 1 hour pad test, but Wille (2003) used a 20 minute provocative pad test.
- Moore et al. (1999b) and van Kampen et al. (2000) set different limits for UI (2 grams as opposed to less than 1 gram).
- Bladder or voiding diaries recording patient-reported symptoms of UI (the second primary outcome of interest in this review) were used in seven of the trials (Bales et al., 2000; Franke et al., 2000; Mathewson-Chapman, 1997; Moore et al., 1999b; Parekh et al., 2003; Porru et al., 2001; Van Kampen et al., 2000).
- One trial (Porru et al., 2001) reported using the American Urological Association symptom score and a five point grading scale to assess strength of pelvic floor muscle contraction by digital evaluation.
- Definitions of UI, on which the number of patients remaining incontinent at the end of the trial was based, varied from the use of pads (Bales et al., 2000; Parekh et al., 2003) to a specified amount of urine lost (Van Kampen et al., 2000). Many authors did not specify a definition of UI for their trial.

Secondary outcomes for this review pertaining to quality of life issues were included in some trials, but the findings were often provided as a narrative summary rather than numerically, and so were not available in a form suitable for statistical analysis. No trials reported on economic issues.

Methodological Quality of Included Studies

The quality assessment criteria of the Cochrane Incontinence Group assume that the avoidance of bias is best achieved by: a randomised trial with secure concealment of allocation prior to formal entry; adequate blinding of patients, outcome assessors and health care providers; description of reasons and numbers of withdrawals and dropouts; and analysis on an intention to treat basis. None of the early trials fulfilled all these criteria. However recent trials have fared much better in terms of secure concealment of allocation and blinding. Overall, the quality of trials included in the review was low to moderate.

Concealment of allocation of randomization. Although all sixteen studies were identified as randomised controlled trials, only seven (Burgio et al., 2006; Filocamo et al., 2005; Hoffmann et al., 2005; Moore et al., 2006; Moore et al., 1999b; Moore et al., 2004; Van Kampen et al., 2000) clearly described that a secure technique of concealment of allocation had been used (e.g. sealed envelopes or computerized randomisation).

Blinding. Blinding was not described in most of the trials, with just a handful indicating an attempt to minimize bias in intervention or outcome measurement. Bales (2000) and van Kampen et al.(2000) had people not involved in provision of the intervention act as outcomes assessors. Moore indicated that a single therapist, blinded to control group outcomes, provided all treatment (Moore et al., 2006; Moore et al., 1999b).

Burgio et al.(2006) and Moore et al. (2006) also reported blinding interventionists or evaluators.

Withdrawals and dropouts. Bales et al. (2000) and Mathewson-Chapman (1997) do not mention withdrawals or dropouts: there are apparently no dropouts in the first of these two trials, but the issue is unclear in the second trial. All others reported the number of withdrawals or dropouts, but the reasons were not consistently reported. Only two trials discussed how this was dealt with in the analysis (Moore et al., 1999b; Parekh et al., 2003).

Quality assessment scale. The Jadad scale was also used for measuring quality (Jadad et al., 1996). Two studies (Burgio et al., 2006; Moore et al., 2006) scored 4/5 on this scale, two studies (Dubbelman et al., 2004; Moore et al., 1999b) received 2/5 points on this scale, three trials (Franke et al., 2000; Parekh et al., 2003; Van Kampen et al., 2000) received 1 point, and the rest received a score of zero. This reflects the lack of adequate information on randomisation technique and failure to mention or inadequate blinding in reports on most of the trials or from information supplied by the researchers to the authors of the review.

Reporting of Outcomes

Most trials appeared to base reporting of primary outcomes on patient reported symptoms such as leakage or pad use, recorded in a bladder diary (Franke et al., 2000), reported on interview (Bales et al., 2000), or measured in a symptom questionnaire (Porru et al., 2001). Six trials reported an objective measure based on the amount of urine lost in a pad test (Hoffmann et al., 2005; Joseph & Chang, 2000; Moore et al., 2006; Moore et al., 1999b; Wille et al., 2003), although the length of the pad test varied from 20 minutes

to 24 hours. Moore et al. (2006) and Van Kampen et al. (2000) set different limits (8 grams as opposed to less than 1 gram). In one trial (Mathewson-Chapman, 1997), this appears to have been derived from a combination of pad test results and patient reported symptoms.

None of the secondary outcomes identified for this review were included in the analysis as few trials reported on these. Five trials reported measures of quality of life or satisfaction, but they were very different measures and not reported in a format that allowed them to be included in analysis. Moore, Griffiths et al. (1999b) used two validated quality of life measures. Although there was a moderate correlation between one measure and the amount of urine lost, there were no differences between intervention and control groups. Satisfaction with the treatment was reported as high, based on face to face interview. Burgio et al. (Burgio et al., 2006) used the Hopkins Symptom Checklist (SCL-90-R) and the Medical Outcomes Study Short Form Health Survey (SF-36), and reported no difference between intervention and control groups in terms of quality of life. Hoffman (2005) used the QLQ-C30 and found improvement in all three groups in terms of quality of life, with most improvement occurring during the time of the rehabilitation program. Porru et al. (2001) used a standardized questionnaire of seven questions, some of which were open-ended allowing for written concerns from participants. The intervention group was found to have a significantly higher satisfaction rate.

Comparisons Based on Interventions

1. Post-operative TURP PFMT versus no treatment or placebo or sham therapy.

One of the included trials (Porru et al., 2001) studied men after TURP for benign prostatic hyperphasia comparing PFMT with no treatment. The primary outcome was

number remaining incontinent at one month after operation. The men started the intervention protocol on the first or second day postoperatively at the time of catheter removal, with the intervention group taught to perform PFMT daily at home (varying frequency) with weekly digital anal reassessment and grading of pelvic muscle contraction by the therapist.

Number not cured. There were no significant differences between the groups in the rates of men incontinent at less than three months and confidence intervals were wide (Figure 3-1).

2. Post-operative TURP PFMT plus biofeedback versus PFMT alone.

No trials were identified.

3. Post-operative RP PFMT versus no treatment or placebo or sham therapy.

Three of the included trials (Dubbelman et al., 2004; Filocamo et al., 2005; Moore et al., 1999b) compared PFMT with no treatment amongst men after RP, and reported data on the review primary outcomes. The Moore trial (Moore et al., 1999b) involved men incontinent eight or more weeks postoperatively (some were recruited more than a year after surgery), and may represent a group with persistent UI and perhaps more complex underlying reasons for UI. In this trial, the active intervention group underwent twice weekly PFMT exercises under the direction of a physiotherapist (Moore et al., 1999b). Dubbelman et al. (2004) randomised men who had undergone RP who remained incontinent one week after catheter removal to physiotherapy guided pelvic floor exercises or to a control group, who received instruction for exercises through an information folder. Participants in the Filocamo et al. (2005) study were randomised to two groups following catheter removal post RP. The intervention group participated in a

structured PFMT program of three treatment sessions and home exercises, with the control group receiving no formal instruction.

Number not cured. Although men undergoing active treatment were less likely to be incontinent at each time period up to 12 months (eg RR 0.50, 95% CI 0.40 to 0.62 at 6 months (Figure 3-2) (Dubbelman et al., 2004; Filocamo et al., 2005; Moore et al., 1999b), the results were influenced by data from the only large trial (Filocamo et al., 2005), which contributed to the high heterogeneity at 6 months ($P<0.001$, $I^2 = 92.4\%$).

Pad test. Two of the studies (Filocamo et al., 2005; Moore et al., 1999b) reported 24 hour pad test results. For the Filocamo et al. (2005) trial, the 24 hour pad test data were not published, but the author was contacted and provided this data. The third study (Dubbelman et al., 2004) also measured urine lost on the 24 hour pad test, but did not report standard deviations and could not be included. There were no significant differences between the groups in terms of amount of urine loss estimated from pad tests at 3, 6 and 12 months, and the standard deviations (SDs) were often larger than the means, suggesting highly skewed data (Figures 3-3 and 3-4).

These findings should be interpreted with caution as two of the trials were small, and one recruited men at variable time periods post-operatively. However, the larger trial did suggest some useful effect of PFMT in the post RP population.

4. Anal electrical stimulation versus no treatment or placebo or sham therapy.

No trials were identified.

5. Transcutaneous electrical nerve stimulation (TENS) versus no treatment or placebo or sham therapy.

No trials were identified.

6. Preoperative RP PFMT plus biofeedback versus no therapy or sham therapy.

Two trials (Bales et al., 2000; Burgio et al., 2006) compared pre-operative PFMT plus biofeedback with a no-treatment or placebo-treatment control group. In the Bales trial, randomisation occurred preoperatively and initial instruction on PFMT and biofeedback training (surface electrodes) for the intervention group was provided two to four weeks prior to retropubic prostatectomy (Bales et al., 2000). The control group received only postoperative verbal instruction on PFMT, and both groups were encouraged to practice PFMT four times daily once the catheter was removed at two weeks after surgery. Burgio et al. (2006) randomised men choosing to undergo RP to a single pre-operative session of biofeedback assisted PFMT and daily PFMT, or to a control group of usual care with simple instructions to interrupt the stream when voiding.

Number not cured. Both studies reported on UI rates in some way, although statistical advice was sought for the (Burgio et al., 2006) data as it was originally reported by survival curve (time to continence). Data were pooled as there was no significant heterogeneity but the confidence intervals were wide. There was not enough evidence to support or refute active treatment (Figure 3-5).

7. Pre and post operative RP PFMT plus biofeedback versus no therapy or sham therapy.

In one small trial (Parekh et al., 2003) attempted an intervention of both pre and post-operative PFMT plus biofeedback (digital or anal-probe) compared to no intervention in men undergoing RP. Participants randomised to the intervention group were given two physical therapist-led treatment sessions, which included PFMT and digital or anal-probe biofeedback, prior to surgery and every three weeks for 3 months post-operatively, as well as home exercises.

Number not cured. Data at less than 3 months, 3-6 months and within 6-12 months favoured intervention, but results were not significant. Confidence intervals were wide, particularly at the 6-12 month time period (Figure 3-6).

8. Post-operative RP PFMT plus biofeedback versus no therapy or sham therapy.

Four trials compared post-operative PFMT plus biofeedback with a no-treatment or placebo-treatment control group (Franke et al., 2000; Mathewson-Chapman, 1997; Moore et al., 2006; Van Kampen et al., 2000) in men who had undergone RP. In the Franke et al. (2000) trial the intervention group starting PFMT with biofeedback (perineal patch electromyography through weeks 6, 7, 9, 11 and 16 postoperatively), supplemented with home exercises. The control group received no instruction. This was a small trial, with a high drop out rate. Mathewson-Chapman (1997) had the intervention group perform PFMT with biofeedback (anal probe) at home from weeks 3 to 12 after surgery, whereas the control group received no treatment. In a recent study, Moore et al (2006) recruited 217 men from 3 centres with early stage prostate cancer scheduled for radical retropubic prostatectomy. At 4 weeks post surgery, both intervention and control groups received standardized verbal and written instruction about PFMT by one dedicated physiotherapist or registered nurse at each site. The treatment group further received a maximum 24 weekly, 30-minute treatments and home exercises. The control group had no active treatment but did have weekly telephone contact by a urology nurse. Van Kampen et al. (2000) recruited 102 men who were incontinent after catheter removal, and 7 of 50 men received additional anal electrical stimulation if their contractions were found to be weak. In addition men in both groups received bladder training. The control group received placebo (skin) electrostimulation.

Number not cured. Four trials (Franke et al., 2000; Mathewson-Chapman, 1997; Moore et al., 2006; Van Kampen et al., 2000) reported on UI rates up to 6 months. The data at three months or less favoured the intervention (RR for failure 0.73; 95% CI 0.61 to 0.88) (Figure 3-7) However, there was statistically significant heterogeneity (P=0.01, I^2=72%) at this point. There were no significant differences at 6 months pooling all four studies (RR 0.91, 95% CI 0.67 to 1.24) (Figure 3-7), or at 12 months (RR 0.94, 95% CI 0.63 to 1.39) (Figure 3-7) (Moore et al., 2006; Van Kampen et al., 2000) pooling the two studies with the longest follow-up. Three of the trials were small.

Pad changes over 24 hours. One trial (Mathewson-Chapman, 1997) reported on pad changes over a 24 hour period at 3 and 6 months. There were no significant differences between intervention and control (Figure 3-8)

Pad test. Two trials reported on the 24 hour pad test (Mathewson-Chapman, 1997; Moore et al., 2006) as outcome measures. Standard deviations were larger than means in both trials, indicating skewed data. There were no significant differences between intervention and control groups (Figure 3-9).

Episodes of UI. Although there were fewer UI episodes in the intervention group in one small trial, this was not statistically significant (Mathewson-Chapman, 1997) (Figure 3-10).

Trial differences. There was clinical heterogeneity regarding UI status at baseline, timing of recruitment and intervention, content of intervention and control treatments. Franke et al. (2000) used percentage of participants pad free to define continence, while Mathewson-Chapman (1997) does not specify whether the UI rates are based on objective or subjective data. Moore et al. (2006) define continence as <8 gm of urine loss

on 24 hour pad test as well as subjectively as reported by participants as 'yes' or 'no'. Van Kampen et al.(2000) used subjective report and amount of urine lost on pad test (2 grams). There was a high drop out rate in the Franke et al. (2000) trial.

Because of this heterogeneity, it is questionable whether or not the data from the trials should be used to derive summary estimates, and this should be borne in mind when interpreting the data. When the trials are considered individually, there are statistically significant differences following the intervention only in the van Kampen et al. (2000) trial, but not in the other trials.

9. Post-operative RP PFMT plus biofeedback versus PFMT alone.

Two trials (Floratos et al., 2002; Joseph & Chang, 2000) compared use of machine-led biofeedback to augment PFMT versus exercises taught using the standard method of verbal feedback from digital anal assessment. The verbal feedback group was treated as "PFMT alone" for the analysis. Both trials were small for a total of 52 subjects. One was reported as a pilot study only and included one man who had had a TURP rather than RP (Joseph & Chang, 2000). Patients who were incontinent at least six months after surgery were randomised to either the biofeedback or verbal feedback groups. The results were not published, but the author supplied raw data on the pad test results so that means and standard deviations could be calculated by the review authors. Two men (of four still followed up) in the biofeedback group had urine loss on the pad test compared to none of three in the verbal group after three months (Figure 3-11). There are many potentially confounding variables in this trial, acknowledged by the author. Also, as all the men had been incontinent for some time after surgery, they may represent a group with persistent UI.

In the other trial, Floratos et al. (2002) randomised 42 men with post RP UI to PFMT with biofeedback (n=28) or to verbal feedback (n=14), one week after catheter removal. There were no significant differences between the groups, but data were too few to be reliable (Figures 3-12).

10. Post-operative RP PFMT plus anal electrical stimulation versus no treatment or placebo or sham therapy

One trial reported using PFMT with anal electrical stimulation (Moore et al., 1999b). This was the second intervention group in this trial.

Number not cured. There were no statistically significant differences between the groups in terms of reported UI symptoms (Figure 3-13).

24 hour pad test. There were no statistically significant differences between the groups on grams of urine lost (Figure 3-14). SDs were large, indicating skewed distribution of data, and the confidence intervals were wide.

11. Post-operative RP PFMT plus anal electrical stimulation versus PFMT alone.

Three trials (Hoffmann et al., 2005; Moore et al., 1999b; Wille et al., 2003) addressed this comparison. One trial (Moore et al., 1999b) reported two arms with a total of 37 men. Two arms of a three arm trial by Hoffman et al. (2005) also examined this aspect. Hoffman et al. (2005) randomised men remaining incontinent after RP to three arms. In the third trial (Wille et al., 2003), all men received postoperative physiotherapy for 6 weeks after surgery, supplemented by anal electrical stimulation in the second subgroup, and anal electrical stimulation plus biofeedback in the third.

Number not cured. There was no difference in UI rates in the Moore, Griffiths et al. (1999b) trial, but confidence intervals were wide (Figure 3-15).

20 minute pad test. Wille (2003) reported on a 20 minute provocative pad test. Results favoured PFMT with anal ES at both 6 and 12 months, but the earlier result was not significant and confidence intervals were wide. At 12 months men receiving supplementary anal electrical stimulation were significantly drier (WMD -3.31 gms urine loss, CI -6.07 to -0.55) (Figure 3-16).

1 hour pad test. Hoffman et al. (2005) reported on a 1 hour provocative pad test. There were no significant differences between intervention and control groups (Comparison Figure 3-17).

24 hour pad test. In the Moore, Griffiths et al. (1999b) trial, PFMT alone (without electrical stimulation) marginally favoured at 6 months but not at 3 or 12 months, although the distribution of pad test results was very skewed (Figure 3-18).

12. Post-operative RP PFMT plus perineal electrical stimulation versus PFMT alone.

Two arms of the Hoffman et al. (2005) study examined this comparison.

1 hour pad test. Hoffman et al. (2005) reported on a 1 hour provocative pad test. Although results favoured intervention, the difference was not significant and SDs were larger than means, suggesting skewed data (Figure 3-19).

13. Post-operative RP PFMT plus anal electrical stimulation plus biofeedback versus no treatment or placebo or sham therapy.

One trial reported using PFMT with anal electrical stimulation as well as biofeedback (Opsomer et al., 1994). Incontinent men (loss of more than 1 gram of urine on pad test) at six weeks after RP were randomised to intervention and control groups. The intervention group had two sessions of biofeedback and electrical stimulation (type unspecified) in addition to continuing the PFMT taught to both intervention and control

groups earlier after surgery. There were no significant differences between the groups for cure rates, but this was based on only four men having UI at 3 to 6 months (Figure 3-20). Pad test results were not reported in a form that could be used and attempts to contact the author were unsuccessful.

14. Post-operative RP PFMT plus anal electrical stimulation plus biofeedback versus PFMT alone.

Two arms of the Wille et al. (2003) trial addressed this comparison. Data from the 20-minute pad test at 12 months suggested that men in the group using anal electrical stimulation and biofeedback in addition to PFMT lost 3 grams less urine (WMD -3.27, 95% CI -6.03 to -0.51) (Figure 3-21), but the trial was small. There is difficulty comparing the results of the 20 minute pad test to the longer pad test, so clinical relevance of 3 grams of urine loss is difficult to determine. The cost of the extra equipment required to deliver the supplementary interventions was addressed, but a formal economic analysis was not performed.

15. Post-operative RP anal electrical stimulation versus perineal electrical stimulation.

Two arms of the Hoffman et al (2005) examined this comparison. On the one hour pad test, perineal electrical stimulation was favored over anal, but confidence intervals were wide (WMD 4.3, 95% CI -30.06 to 38.66) (Figure 3-22).

16. PFMT plus transcutaneous electrical nerve stimulation versus PFMT alone.

No trials were included. One study (Ceresoli et al., 2002) previously listed as ongoing was excluded attempts to contact the author for data were not successful.

17. PFMT versus transcutaneous electrical nerve stimulation alone or biofeedback alone or anal electrical stimulation alone or no treatment.

No trials were identified.

18. Lifestyle adjustment versus no therapy or sham therapy.

No trials were identified.

19. Extracorporeal magnetic innervation versus no therapy or sham therapy.

No trials were identified. One study (Nehra et al., 2001) previously listed as ongoing was excluded as attempts to contact the authors for data were not successful.

20. External penile compression devices (penile clamp) versus no therapy or sham therapy.

One trial compared three different penile compression devices (Cunningham clamp, U-Tex Male Adjustable Tension Band and C3 penile compression device) with a control period of no device (Moore et al., 2004). A randomised block assignment was used with a multiple period crossover design, so that each of the 12 participants had a control period of no device and three periods in which the different devices were used. All external compression devices reduced the weight of urine lost on a four-hour pad test compared to the control period ($P<0.05$), but none completely eliminated urine loss. Satisfaction was based on ease of application, comfort and efficacy. The device preferred by the largest number of men was also that with the lowest urine loss (Cunningham). However, this was also the device with the greatest reduction in systolic blood flow velocity ($P<0.05$ versus control period), raising the possibility of safety issues if applied too tightly. In the trial, men were able to judge when to release the device, and the authors recommended that its use should therefore be limited to men who are cognitively intact, are aware of bladder filling, have normal genital sensation and intact penile skin, and have sufficient manual dexterity to open and close the device.

Sensitivity Analysis

In the last review, scores from the Jadad scale for each trial were entered into RevMan under the order column in an overall analysis and the resulting forest plot ordered by this score. In this update it was not possible to enter all sixteen studies into a single comparison due to the variety of outcomes reported. The twelve studies (Bales et al., 2000; Burgio et al., 2006; Dubbelman et al., 2004; Filocamo et al., 2005; Franke et al., 2000; Mathewson-Chapman, 1997; Moore et al., 2006; Moore et al., 1999b; Opsomer et al., 1994; Parekh et al., 2003; Porru et al., 2001; Van Kampen et al., 2000) which reported dichotomous data and included in *comparisons of number not cured* were entered into a comparison using data from the endpoint of each of the studies. The Jadad scores for each were entered under the order column and the forest plot generated. With the exception of Filocamo et al. (2005), studies judged to be of poorer quality by this scale (Bales et al., 2000; Filocamo et al., 2005; Franke et al., 2000; Mathewson-Chapman, 1997; Opsomer et al., 1994; Parekh et al., 2003; Porru et al., 2001), usually due to deficit in or absent description of blinding or randomisation method, had wide confidence intervals. Four of the studies (Filocamo et al., 2005; Parekh et al., 2003; Porru et al., 2001; Van Kampen et al., 2000) judged to be of poorer quality favoured intervention of some kind and the other four (Bales et al., 2000; Franke et al., 2000; Mathewson-Chapman, 1997; Opsomer et al., 1994) favoured control. Studies of modest or better quality had narrower confidence intervals. Three of these studies (Burgio et al., 2006; Dubbelman et al., 2004; Moore et al., 1999b) slightly favoured some type of intervention, with one (Moore et al., 2006) favouring control. It does not appear that studies of poorer quality are influencing the overall results of the review. However, this

approach to sensitivity analysis should be viewed cautiously for several reasons. First, not all the studies were included. Second, of those included, there was significant statistical heterogeneity (Chi square = 38.83, P<0.0001) as well as clinical heterogeneity (differences in interventions and samples) which supports not pooling the studies. Finally, the Cochrane Handbook (Higgins et al., 2003) cautions against the use of quality scales as their use is not supported by empirical evidence.

Potential for Publication Bias

Potential for publication bias was examined graphically using a funnel plot. Using the dichotomous data from the same 12 trials included in the comparison for the sensitivity analysis, a funnel plot (relative risk, fixed effects) was generated in MetaView. Considerable funnel plot asymmetry was present, with the smaller trials favouring treatment missing from the left of the funnel, but those favouring control present. Since small studies usually tend to overestimate rather than underestimate the effect of an intervention (Sterne, Egger, & Davey Smith, 2001), attributing the asymmetry to publication bias remains counterintuitive. Again, the more plausible explanation of funnel asymmetry lies in the poor quality of the studies or in true heterogeneity (variations in treatment type or intensity or risk differences attributable to studies of different sizes) (Higgins et al., 2003). As there were only sixteen trials included in this review, no statistical analysis to examine publication bias was undertaken. In meta-analyses of less than 20 trials, sensitivity of these methods (rank correlation or linear regression) is considered low (Sterne et al., 2001).

Discussion

This review incorporates a broad array of possible interventions under the umbrella term of conservative management of postprostatectomy UI. The populations studied included men undergoing prostatectomy for different reasons (both benign and malignant disease). As well, the studies differed on whether they occurred preoperatively, post operatively or at both of these times. Some early studies (Joseph & Chang, 2000; Moore et al., 1999b) included men who had been incontinent for some time (up to months) after surgery. More recent studies have focused on the preoperative or post operative period immediately after catheter removal. Seventeen trials met the inclusion criteria, 16 trials amongst men after RP and one trial after TURP. There was considerable variation in the interventions, populations and outcome measures. Given this clinical heterogeneity it was decided to differentiate the studies, and the comparisons, by timing of the intervention time periods (pre-operative, post-operative or both) and by type of surgery (TURP or RP) in this new update of the review. The majority of trials in this area continue to be of modest quality. However, three recent trials (Burgio et al., 2006; Filocamo et al., 2005; Moore et al., 2006) have been of higher quality in terms of randomisation, blinding and larger numbers. Data were not available in all the trials for many of the pre-stated outcomes. Confidence intervals have tended to be wide except for the more recent studies, and it continues to be difficult to reliably identify or rule out a useful effect. All the trials claimed to be randomised, and seven provided details of adequate concealment of randomization (Burgio et al., 2006; Filocamo et al., 2005; Hoffmann et al., 2005; Moore et al., 2006; Moore et al., 1999b; Moore et al., 2004; Van Kampen et al., 2000). Blinding to intervention was not possible, and blinding of outcome

assessment appeared to be absent in many trials as it was not discussed. Therefore, many of the included trials, especially the early ones, were vulnerable to allocation, intervention and measurement biases.

Attrition bias may have played a role in the results of some of the included trials and therefore affected the outcome of this review. One of the smaller trials (Franke et al., 2000) lost half of the randomised participants by the end of the data collection period. Although most of those trials that lost participants provided an explanation of these losses, none accounted for the missing data in their analyses. The intention to treat principle mandates, at minimum, that patients stay in the group to which they are randomised (Juni, Altman, & Egger, 2001), which the included trials appeared to do. It is also suggested that primary outcomes for all patients randomised to groups should be recorded or estimated if not available. Three of the included trials (Filocamo et al., 2005; Moore et al., 2006; Parekh et al., 2003) reported an analysis using the intention to treat principle, and one trial (Burgio et al., 2006) used survivor analysis in the original study analysis. However, attrition bias is possible in a number of the other trials which do not discuss the issue.

Few trials used the primary outcomes of interest, patient reported symptoms and the standardized pad test. Most appeared to use a variety of subjective outcomes derived from patient reported symptoms in determining whether or not continence was achieved. There were no trials which examined lifestyle adjustments in alleviating UI after prostatectomy.

There may be some enhancement of quality of life in men after prostatectomy through the support provided by attending a clinic offering these interventions (Moore et

al., 1999b). Hoffman et al. (2005) also measured quality of life, and did not find a difference in this outcome between the 3 groups studied in rehabilitation programs, reporting that all groups improved on continence and quality of life, but that quality of life improvement was mostly achieved during the inpatient rehabilitation period which might also suggest some effect of being in a program. Burgio et al. (2006) also included a quality of life measure.

It is acknowledged that postprostatectomy UI will resolve over time in many men, and all the trials demonstrated this. There was some subjective support from three trials that post operative PFMT alone was better than no treatment up to 6 months after treatment (Figure 3-2, 3-3), although this was not strongly supported by differences in pad tests (Figure 3-4). However, there was insufficient evidence to conclude that supplementing PFMT with biofeedback, whether pre- or post-operatively, was helpful or not (Figure 3-5, 3-6, 3-7). Only two trials, Filocamo et al. (2005) without biofeedback and van Kampen et al. (2000) with biofeedback, were individually in favour of active treatment.

Data from trials which examined anal or perineal electrical stimulation were also inconclusive. There were no trials which examined other conservative interventions such as transcutaneous electrical nerve stimulation, lifestyle interventions or extracorporeal magnetic innervation. There were too few data to determine effects on UI after TURP. The findings should continue to be treated with caution as there were few studies, most of poor to moderate quality. Men in one trial reported a preference for one type of external compression device (penile clamp) compared to two others or no treatment. Men's symptoms tended to improve over time, irrespective of management.

The effectiveness of conservative measures in the longer term, or in those with persistent UI, remains inconclusive. Although two trial (Burgio et al., 2006; Filocamo et al., 2005) reported benefit based on subject recorded outcomes, when the data were entered into RevMan, no significant differences were found. However, one particular type of alternative intervention, a Cunningham clamp fitted to the shaft of the penis, proved satisfactory to 10 of 12 men with intractable UI (Moore et al., 2004). This may be a viable alternative for some cognitively capable men providing they take into account safety issues such as adequate sensation and ability to remove the device when it feels too tight or the bladder is full.

Conservative interventions tend to be resource-intensive strategies that require people, equipment and clinic space, so administrators will look for evidence of efficacy. Funding has been an issue given the inconclusive nature of the evidence to date. For example, in the United States, the centres for both Medicare and Medicaid Services were considering whether to withdraw funding for biofeedback and pelvic floor electrical stimulation in the treatment of UI of any etiology based on a lack of evidence regarding effectiveness. Through a lobbying effort from service providers and manufacturers, these modalities continued to be covered (Thompson, 2002). As controversy about funding is likely to continue, there is a need for continued research in the area to determine which groups of patients are most likely to benefit from conservative interventions.

Reviewers' Conclusions

Implications for Practice

In keeping with conclusions from earlier versions of this review, at this point there remains no clear support that conservative management of any type for

postprostatectomy UI is either helpful or harmful. The most promising evidence of benefit is in patients with RP, where PFMT early in the postoperative period immediately following removal of the catheter may promote an earlier return to continence and potentially some improvement for a few in the longer term. However, these findings are dependent on a small number of trials. No trials have tested the effect of lifestyle changes alone. Long-term UI may be managed by external penile clamp, but there are safety problems.

Implications for Research

Postprostatectomy UI is a distressing problem and, although conclusive evidence does not exist, conservative approaches form part of current management. Clinical trials with improved methodology are needed to clarify the role of these therapies.

As there are known differences in the causes and prevalences of UI between men after TURP and after RP, these groups of men should continue to be studied separately. One promising area is the potential for a quicker return to continence from pre-operative or early postoperative treatment.

Most of the trials included in this review used very different protocols of intervention type, timing and intensity. In order to determine the effects of specific protocols and modalities, large adequately powered trials using common protocols are needed. Replication studies using similar protocols in different populations would also assist in identifying the populations in which specific conservative management approaches are likely to be most effective.

Definitions and measurement of outcomes varied in the included trials. Future trials should attempt to use broadly accepted definitions, such as those of the

International Continence Society and to make use of objective measures such as the pad test in determining if continence has been achieved. Researchers must also focus on either the 1 hour or 24 hour pad test, as the results of these two measurements are not equivalent.

Lastly, authors of trials on conservative management of UI should be encouraged to ensure appropriate randomisation and blinding of trials and to report these adequately in published reports of their work, using the guidelines of the CONSORT statement (Moher, Schulz, & Altman, 2001).

Table 3-1

Characteristics of Included Studies

Study	Methods	Participants	Interventions	Outcomes	Notes	Allocation concealment
Bales 2000	Randomised: yes Method of allocation: not stated Blinding: Outcome assessment nurse not involved in intervention. Dropouts: None mentioned.	N=100 consecutive patients with stage T1c-T2c prostate cancer undergoing radical retropubic prostatectomy by a single surgeon randomised into 2 groups.	Pre operative intervention. Intervention group: 2-4 weeks prior to surgery, participants underwent a 45-minute session with nurse trained in biofeedback. Patients were instructed to perform graded PFMT. Contractions of 5-10 seconds, 10-15 repetitions were performed with surface electrodes used to measure muscle strength. Advised to practice the exercises 4 times per day until surgery. Control: No biofeedback	Time to return of continence measured by number of pads used Continence defined as use of 1 pad or less per day Data collected at 1, 2, 3, 4, and 6 months postoperatively.	There was no significant difference in incontinence between the groups.	B

Study	Methods	Participants	Interventions	Outcomes	Notes	Allocation concealment
			training. Written and brief verbal instructions from a nurse on how to perform PFMT (isolate muscle that stops urine flow, practice 4 times per day, 10-15 repetitions). Both: Encouraged to perform PME 4x per day after catheter removal 2 weeks post op.			
Burgio 2005	Randomised: yes Method of allocation: stratified by age and tumor differentiation, then randomised using computer generated random numbers, block size of 4 to ensure equity of number in each group.	N=125 volunteer patients randomised, 13 excluded after randomisation. Analysis on N=112 men aged 53-68 who underwent radical prostatectomy for prostate cancer. To be eligible, the men had to be	Pre operative intervention. Intervention group: Single session of biofeedback assisted behavioural training. Rectal probe to measure (intra-abdominal)rectal pressure and external anal sphincter contraction, and	Both groups taught to record continual and episodic urine loss using bladder diaries. As well, use of incontinent pads or other products were recorded. One day bladder diaries mailed in each week. Participants contacted at 6 weeks, 3 months	Time to continence was significantly reduced in the intervention group. The intervention group had a significantly smaller proportion of those with	A

Study	Methods	Participants	Interventions	Outcomes	Notes	Allocation concealment
	Blinding: Intervention providers and bladder diary scorers were blinded. Dropouts: 6 participants in the intervention group, and 7 in the control were excluded after randomisation as surgery was cancelled. At 6 months, 6 in the intervention and 4 in the control were lost to follow-up.	ambulatory, continent and identied at least 1 week prior to their surgery.	provide feedback to participants. Feedback and verbal instruction used to teach control of pelvic muscles. Taught to contract sphincter during 2-10 seconds periods separated by 2-10 seconds of relaxation, dependent on ability. Written instructions provided for daily at home practice of 45 PFM exercises daily (3 sessions of 15 exercises each time). Additionally instructed to slow or interrupt voiding once daily. Encouraged to exercise daily preoperatively, then resume when catheter removed	and 6 months post surgery to complete questionnaire on bladder control and lifestyle, 7day bladder diary . Impact of incontinence and quality of life measured pre-operatively and at the follow-up contacts by IIQ, SCL-90-R and SF-36. Continence defined as 3 consecutive weekly 1 day diaries showing no leakage or a 7 day diary showing no leakage.	severe or continual leakage at 6 months, and stress type urine loss. No differences on quality of life, return to work or activities between the groups. Analysis by "intention to treat".	

Study	Methods	Participants	Interventions	Outcomes	Notes	Allocation concealment
			post-operatively. Control group: usual care consisting of brief verbal instructions post operatively to interrupt the voiding stream plus any instruction from their physician.			
Dubbelman 2004	Randomised: yes Method of allocation: not described. Blinding: not mentioned. Dropouts: 5 were excluded after consent (3 had positive nodes, 2 were not incontinent). Of the 70 men incontinent one week after catheter removal who were randomised to two groups, 7	N=63 men completing the study, 31 in intervention group, 32 in control. All participants had a radial retropubic prostatectomy and lived within 75 km of hospital. Age range 61-67 years.	Post operative intervention. Intervention group: 9 or less sessions of physiotherapy guided pelvic floor exercises after surgery. Control: Exercise instruction through information folder.	1 hour and 24 hour pad tests at 1 and 26 weeks after catheter removal. Urodynamic study (urethral pressure profilometry also completed. Incontinence defined as loss of at least 1 gram of urine on 1-hour pad test or 4 grams on the 24 hour pad test.	No significance difference in continence rates between the groups.	B

Study	Methods	Participants	Interventions	Outcomes	Notes	Allocation concealment
	dropped out due to bladder neck contracture (4), withdrawal of consent (2) or lack of understanding (1).					
Filocamo 2005	Randomised: yes Method of allocation: block randomisation Blinding: not described Dropouts: At 12 months, 2 participants dropped out of the control group. Intention to treat:	N= 300 men post RRP randomized after catheter removal to 2 groups. Intervention group: N= 150 Control group N=150	Post operative intervention. The intervention group received formal instruction (3 treatment sessions plus at home exercises) in PFMT using verbal explanation, palpation and visualization of the base of the penis with a mirror, in different positions and prior to sneezing, coughing or lifting. Contraction evaluated by digital anal contol.	1 hour and 24 hour pad tests plus number of pads used daily at 1, 3, 6, and 12 months.	74% of the intervention group achieved continence at 3 months compared to only 30% of the control (a significant difference favoring intervention). Differences between the groups declined between 6-12 months, with most participants	A

Study	Methods	Participants	Interventions	Outcomes	Notes	Allocation concealment
			The control group received no formal instruction.		achieving continence in 1 year.	
Floratos 2002	Randomised: yes Method of allocation: randomized 2:1 to intervention: control groups. Blinding: Not mentioned Dropouts: 1 participant randomized to intervention unable to follow intervention protocol (unable to attend clinic. Provided with control invention. Intention to treat: yes	N = 42 consecutive patients with post RP UI recruited one week after catheter removal. Intervention N=28 Control N=14	Post operative intervention. Intervention Initiated after catheter removal. Intervention group received 15 sessions (3 times per week for 30 minutes) of PFMT with EMG (surface) biofeedback in clinic. Control group received instruction with verbal feedback and an information pamphlet with instructions to perform PME 50-100 times daily at home.	1 hour pad test and continence questionaire (pads used, number of incontinence episodes) at baseline, 1, 2, 3 and 6 months.	Level of incontinence in both groups declined over the 6 months of the study. Control group had less urine loss and appeared to regain continence sooner, but the difference was not significant.	B
Franke 1998	Randomised: yes Method of allocation: not stated	30 men 6 weeks post radical prostatectomy with post void	Postoperative intervention. Biofeedback enhanced PFMT;	All patients completed a voiding diary, 48 hour pad test, and	There were no significant differences between	B

Study	Methods	Participants	Interventions	Outcomes	Notes	Allocation concealment
	Blinding: none Dropouts: 2 with gravitational incontinence consistent with intrinsic sphincter deficiency Intention to treat: not clear.	residual of <50ml; no previous TURP, no urinary tract infection, no neurological conditions.	exercises provided at 6, 7, 9, 11, and 16 weeks postoperatively; control group completed bladder diary but did not have any other intervention. Duration: 12 months.	incontinence questionnaire at all measurement points.	treatment or control groups on any of the outcome measures. This information is based on an abstract only. The authors did not return the reviewer's telephone calls.	
Hoffman 2005	Randomised: yes (randomly assigned to 3 groups.) Method of allocation: computerized randomization. Blinding: unclear Dropouts: 1 participant from each intervention group had	N= 180 men with post RP urinary incontinence in an inpatient rehabilitation program.	Post operative intervention. Intervention group 1: perineal electrical stimulation plus physiotherapy (PFMT). Intervention group 2: electrical stimulation plus physiotherapy (PFMT). Control group 3:	1 hour pad test as objective assessment at admission and discharge from the rehabilitation program. Quality of life (QLQ-C 30) and subjective reports of continence at admission, discharge and 3	All groups improved on continence and quality of life. Use of electrical stimulation was only of additional value in a compliant subgroup. Perineal	A

Study	Methods	Participants	Interventions	Outcomes	Notes	Allocation concealment
	dropped out by discharge; 15 dropouts from the perineal group, 31 from the anal group and 5 from the control group dropped out by 3 months. Intention to treat: no		PFMT alone.	months.	electrical stimulation was better accepted than anal.	
Joseph 2000	Randomisation: yes Method of allocation: Not described. Blinding: None. Dropouts: 3 did not return to clinic for all appointments, one had other health problems Intention to treat: No.	N= 11 patients at least 6 months post surgery (4 radical retropubic, 6 radical peritoneal, 1 TURP).	Post operative intervention. Biofeedback group: Biofeedback as well as verbal to assist in identifying and discriminating muscles Control: Verbal feedback group received instruction, squeezing of finger during digital rectal exam Both groups received weekly visit for a total of 4	Pretreatment video-urodynamics standardised pad test, Joseph Continence Assessment Tool, bladder diary, subjective estimation of degree of incontinence. Measured at baseline, 3, 6, and 12 months.	No differences between the groups. Improvement seen in all patients at 12 months. Data not published in article. Raw data supplied to reviewer (KFH) who calculated means and standard	B

Study	Methods	Participants	Interventions	Outcomes	Notes	Allocation concealment
			clinic visits		deviations. These were reviewed by a second reviewer (KNM).	
Mathewson-Chapman 97	Randomised: yes, block procedure Method of allocation: unclear Blinding: none Dropouts: 2 - not accounted for. Intention to treat: not clear.	53 men pre and post radical prostatectomy. Preoperatively, both groups received 30 mintues prostate education programme and baseline 'perineal muscle evaluation' (not defined); as well all were taught to contract the perineal muscle and hold for a few seconds prior to standing, lifting or coughing and limit the amount of tea, chocolate,	Postoperative intervention. Group 1 (control) no further interventions until week 5 when pelvic muscle strength was assessed. Group 2: (treatment): Home exercises and biofeedback using (Incare 8900); practiced at home 3 times a week, starting with daily 15 PFMT and increasing by 10 every 4 weeks to a maximum of 35 PFMT. Duration: 12 weeks.	Perineal muscle strength (method not described) frequency of micturitions (self-recorded bladder diary), number of pads used; days to achieve continence from baseline.	Inclusion of other modalities such as caffeine limitation and using pelvic floor muscles during any event which increased abdominal stress in both groups may have masked any treatment benefit.	B

Study	Methods	Participants	Interventions	Outcomes	Notes	Allocation concealment
		alcohol and over-the-counter medications.				
Moore 1999	Randomised: yes Method of allocation: sealed envelopes. Blinding: physiotherapist blinded to results of control group. Dropouts: 5 Intention to treat: yes.	58 men post radical prostatectomy who were a median of 8 weeks post operation (range 4-200 weeks).	Postoperative intervention. Group 1(control) oral and written information about PFMT pre and post-operatively (standard treatment); Group 2: PFMT alone; Group 3: PFMT plus rectal electrical stimulation treated by one physiotherapist 30 minutes twice a week for 12 weeks. Groups 2 & 3 did home exercises three times a day gradually working up to 30 minutes per session lying, standing, sitting; strength, endurance,	24 hour pad test, quality of life measures (Incontinence Impact Questionnaire, European Organization for the research and treatment of Cancer-EORTC QLQ C-30, version 2), physical symptom inventory (adapted from Herr 1994). Measured at baseline, 12, 16 & 24 weeks after baseline.	Intervention perhaps administered too late in some subjects - all subjects improved at the same rate; wide range of severity of urinary incontinence at study entry and size of SD of pad test results also may have resulted in Type II error	A

Study	Methods	Participants	Interventions	Outcomes	Notes	Allocation concealment
			speed and control with maximum contractions of 5-10 seconds, 10-20 second relaxation and 12-20 repetitions; submaximum contractions at 65-75% of maximum strength with hold 20-30 seconds and equal rest time, 8-10 repetitions; speed was sets of quick repetitive contractions in a 10 second time span; control involved gradual recruitment to maximum contraction in 3 stages with 5 second hold at each stage and a slow release with rest 15-30 seconds. Duration of study: 24 weeks.			

Study	Methods	Participants	Interventions	Outcomes	Notes	Allocation concealment
Moore 2004	Randomised: yes (order of product testing: to treatment block of 4 periods (1 no device, 3 with devices) Block, multiple period crossover design using Latin square configuration; Method of allocation: sealed envelopes. Blinding: Research assistant not involved in study chose envelope; but research assistant and participants could not be blinded to intervention Dropouts: None Intention to treat: Not discussed.	N = 12 men post radical prostatectomy who required continuous pad protection for stress incontinence Inclusion: normal perineal and penile sensation, intact penile skin, sufficient manual dexterity Exclusion: overactive bladder, neurological disorders affecting sensation or circulation, cognitive impairment.	Postoperative intervention. Each participant had 4 periods (each lasted 1 day) 1. No device 2. C3 device 3. U-Tex device 4. Cunningham clamp.	4 hour pad test. None of the devices completely eliminated urine loss when applied at a comfortable pressure. Each device showed improvement in terms of urine lost, with Cunningham clamp having the lowest mean loss. Other outcomes: resistive index (no effect), cavernosal flow (Cunningham clamp significantly lowered flow) Cunningham clamp ranked positively by participants.	Unable to blind participants and research assistant to intervention Sample size calculation given and required size achieved.	A

Study	Methods	Participants	Interventions	Outcomes	Notes	Allocation concealment
Moore 2006	Randomised: yes Method of allocation: computer generated list of numbers; group allocation placed in sealed opaque envelopes; opened by subject after initial instruction session with therapist. Blinding: data entry by clerk blinded to group; therapist blinded to outcome of non-intervention group Dropouts: control = 7; treatment = 12	N=217 men from 3 centres with early stage prostate cancer (PSA mean 8.4, SD 10.4; Gleason 6.3 SD .86) scheduled for radical retropubic prostatectomy; assessed preoperatively with IIQ-7, IPSS, 24 hour pad test and voiding diary; English speaking within 1 hour drive of research centre.	Interventions: At 4 weeks post surgery, both groups received standardized verbal and written instruction about PFMT and recovery after radical prostatectomy by one dedicated physiotherapist or registered nurse at each site; treatment group had a maximum 24 weekly, 30-minute treatment protocol and home exercise protocol of 2-3 times a day; non intervention (control) group had no active intervention except weekly telephone contact by a urology nurse.	Outcomes: Primary outcome measure: gm of urine loss on 24 hour pad test; secondary outcome: IPSS, IIQ-7 (Incontinence Impact Questionnaire), voiding diary, and subjective continence. All measures were obtained at baseline (preoperatively) and at 4, 8, 12, 28 weeks and 1 year post operatively. Continence on 24 hour pad test was defined as <8 gm of urine loss on 24 hour pad test; subjective continence defined as yes/no.	Notes: At 8 weeks 21 (23%) control; 21 (20%) treatment were dry; at 12 weeks, 24 (28%) and 32 (32%); at 16 weeks, 33 (40%) and 42 (44%); at 28 weeks, 39 (50%) and 45 (47%); and at 12 months 73% of control and 67% of treatment groups were dry (<8 gm on pad test) . There were also no significant differences between	A

Study	Methods	Participants	Interventions	Outcomes	Notes	Allocation concealment
					groups on IPSS, IIQ-7, or voided diary at any time point post operatively. The majority of subjects reported a low impact of incontinence as per the IIQ-7 and fewer LUTS at 12 months than at baseline as per the IPSS (Table 2). The majority were very satisfied with treatment. No difference between groups	
Opsomer	Randomised: yes	43 men who	Postoperative	Numbers not cured	No statistical	B

Study	Methods	Participants	Interventions	Outcomes	Notes	Allocation concealment
1994	Method of allocation: method not described Blinding: none Drop outs: 4 Intention to treat: unclear.	were still incontinent 6 weeks after prostatectomy.	intervention. Patients who lost more than 1gram of urine on pad test (International Continence Society (ICS) recommenda-tions) 6 weeks postoperatively were allocated to 2 groups; Group 1; 21 PFMT plus biofeedback plus electrical stimulation directed by physiotherapist. Group 2; PFMT on their own without medical supervision. Duration: 12 weeks.	Pad test.	difference between groups as to recovery of continence. Abstract only - previous attempts to contact author unsuccessful in gaining more data.	
Parekh 2003	Randomised: yes Method of allocation: Not described. Blinding: None Dropouts: 1 from each of the control and treatment groups.	N= 38 patients scheduled for radical retropubic prostatectomy for localised cancer of the prostate.	Pre and postoperative interventions: Control group: No formal education on PFMTpre-operatively, telephone or face to face follow-up at	Incontinence measured by number of pads used daily. Continence defined a 0 pads or 1 precautionary pad.	Greater number of the intervention group gained continence earlier than the control group at 3	B

Study	Methods	Participants	Interventions	Outcomes	Notes	Allocation concealment
	Reasons not described. Intention to treat: Yes, dropouts categorised as incontinent.		least monthly. Intervention group: 2 treatment sessions preoperatively. Session 1 consisted of PFMT in a crook lying position. Session 2 was on an exercise ball. Teaching methods varied and included verbal cues, visualization with an anatomical model, palpation or biofeedback with rectal probe. Postoperatively, PFMT was reviewed and participants were seen every 3 weeks for 3 months by a physiotherapist.		months (only point of statistical difference). Minimal long term effect as continence rates the same at 1 year.	
Porru 2001	Randomised: yes Method of allocation: Not described. Blinding: Report	N=58 consecutive patients undergoing TURP for benign	Pre and post operative intervention? Intervention group: Initial visit before	Grading of perineal and anal contraction by digital evaluation of muscle	Significant increase in muscle strength in intervention	B

Study	Methods	Participants	Interventions	Outcomes	Notes	Allocation concealment
	stated that urologist performing digital evaluation of pelvic floor muscle contraction was blinded to the study group. Dropouts: Intervention - 2, control - 1. Reason reported was non-attendance at all clinic appointments. Intention to treat: None.	prostatic hypertrophy.	surgery, digital evaluation of pelvic muscle contraction strength. Verbal instruction, feedback and reinforcement on contraction was given to teach selective contraction of anal sphincter and relaxation of abdominal muscles. Verbal and written instruction given for home PFMT. Instructed to practice contractions 45 times per day (3 groups of 15 contractions). Both groups: Voiding diaries initated after catheter removal.	contraction. Scale 0-4 [0=none, 4=strong]. Urine flowmetry preoperatively and 1 month postoperatively. AUA (American Urological Association) symptom score preoperatively and 30 days after surgery. 48-hour voiding diary weekly. Data collected at catheter removal and weekly for 4 weeks.	group by week 4. Both groups showed improvement in symptom score and quality of life postoperative ly, no significant difference between groups. Significantly better satisfaction with life in intervention group compared to control at 4 weeks. Significant difference in voiding intervals between the groups at	

Study	Methods	Participants	Interventions	Outcomes	Notes	Allocation concealment
					weeks 2 and 3, but not week 4. No difference in uroflowmetry. Significantly less incontinence in the intervention group at weeks 1, 2, and 3. No difference at week 4. Concluded that PFMT quickens the return to normal voiding post TURP.	
van Kampen 1998	Randomised: yes Method of allocation: stratified randomisation	Of 181 men after radical prostatectomy, 16 subjects dry, 63 unable to	Post operative intervention. PFMT and biofeedback after catheter removal versus no	Numbers cured defined as <2gm urine loss 1 hour pad test (subject conducted	Pragmatic study; policy of management left to clinical	A

Study	Methods	Participants	Interventions	Outcomes	Notes	Allocation concealment
	with sealed envelopes. Blinding: yes Dropouts:5. Intention to treat: yes Outcome assessor not involved with the study.	attend clinic (lived too far away), remainder (N=102 eligible) randomised on day of catheter removal; stratified by gms of urine loss (<50 , >50, <250, >250 gm)	systematic PFMT Group 1 had 1 session of PFMT in hospital before discharge and saw the physiotherapist for 1-2 weeks for as long as UI persisted and 90 daily home exercises sitting, standing and lying. 7 men received electrical stimulation Group 2 did not receive any formal PFMT instruction but saw the therapist at 1-2 weeks and received placebo stimulation and information about aetiology of UI Both groups received bladder training to increase bladder capacity Duration: 12 months	in the home) Number of days to continence Visual Analogue Scale, Fluid Volume Chart, Quality of Life questionnaire designed for the study.	judgment as to which protocols to add to PFMT regime. 63 of the eligible subjects were unable to participate because of geographical reasons; demographic s and post-operative variables did not differ from the 102 subjects who were in the treatment groups. Significant differences at 3 months, but not sustained.	

Study	Methods	Participants	Interventions	Outcomes	Notes	Allocation concealment
Wille 2003	Randomised: yes Method of allocation: Not described Blinding: Not mentioned Dropouts: Numbers participating at 3 and 12 months identified (for pad test, N= 116 at baseline, 79 at 3 months and 124 at 12 months), reason for dropouts not described.	N= 139 men scheduled for RP. Recruited preoperatively at the hospital, randomised to 3 groups after consent obtained.	Post operative intervention. All participants: PFMT by physiotherpist, 20-30 minute sessions for 3 days, instructed to perform exercises twice daily for 3 months plus3 week rehabilitation program after discharge. Regular interaction with health professional for 6 weeks after surgery, encouraged to performed treatment for 3 months post surgery. Intervention group 1: PFMT + ES. PFMT as above plus instructed by dedicated in ES via surface anal electrode and	Continence questionaire and 20 minute provocative pad test at baseline (after catheter removal), 3 months and 12 months post operatively.	No significant differences in continence rates between the three groups at baseline, 3 months or 12 months. Continence defined as reported use of 0-1 pads on questionaire (subjective) or loss of less than 1 gram of urine on pad test (objective).	B

Study	Methods	Participants	Interventions	Outcomes	Notes	Allocation concealment
			bioimpulser (biphasic pulse with 1 second bursts, 5 second pulse width, 2 second pulse train. Intervention group 2: PFMT + ES + biofeedback. As above plus biofeedback (anal probe) 15 minutes twice daily for 3 months. Control group: PFMT alone.			

PFMT=pelvic floor muscle training; UI=urinary incontinence; TURP=transurethral resection of the prostaste; gm(s)=gram(s)

Table 3-2

Characteristics of Excluded Studies

Study	Reason for exclusion
Bennett 1997	Abstract only, no data included. Attempts to contact the author for data unsuccessful.
Bocker 2002	Data from study that included male postprostatectomy and female post-polio patients. Translation obtained as reported in German. Data from the two groups were not separated and therefore not in a usable form.
Ceresoli 2002	Attempts to contact the author for data unsuccessful.
Chang 1998	Data from study which involved post TURP patients. Two groups, treatment and control. Not randomly assigned to groups, first 25 consecutively assigned to control, next 25 to intervention.
Cornel 2005	Descriptive study. No control group.
Crevenna 2003	Descriptive pilot study. No control group.
Griebling 1999	Data reported in paper presentation and in later published report did not contain sufficient detail of analysis to include in tables of comparison. Attempts to contact authors not successful in providing further data.
Ip 2004	Education intervention (refrigerator magnet), not an intervention included in review.
McGlynn 2004	Descriptive study of change in education delivery approach. No control group.
Nehra 2001	Abstract only. Attempts to contact authors for further data unsuccessful.
Pulker 2002	Descriptive study. No control group.
Salinas Casado 1991	Descriptive study. No control group. Article in Spanish with English abstract.
Salinas Casado 1996	Descriptive study. No control group. Article in Spanish with English abstract.

Study	Reason for exclusion
Seki 2005	Descriptive study. No control group.
Yokoyama 2004	Data not in usable format for inclusion in tables of comparison. Lead author contacted, but no further data other than that published was available.
Zermann 1999	Descriptive study. No control group.

TURP=transurethral resection of the prostate

Table 3-3 Characteristics of ongoing studies

Study	Trial name or title	Participants	Interventions	Outcomes	Starting date	Contact information	**Notes**
Glazener 2004	Conservative treatment for urinary incontinence in men after prostate surgery (MAPS)	Men after radical prostatectomy (RP)and endoscopic resection of prostate (ERP)	Plevic floor muscle training and bladder training	Urinary incontinence, faecal incontinence, sexual function, quality of life, economic outcomes	Autumn 2004	Glazener CMA c.glazener@abdn.ac.uk	Duration of trial 4.5 years

Figure 3-1. Post-operative TURP PFMT vs no treatment or placebo or sham (number not cured)

Study	PMFT	Control	RR	Weight	RR (fixed)
or sub-category	n/N	n/N	95% CI	%	95% CI
Less than 3 months					
Porru 2001	1/30	3/28		100.00	0.31 [0.03, 2.82]

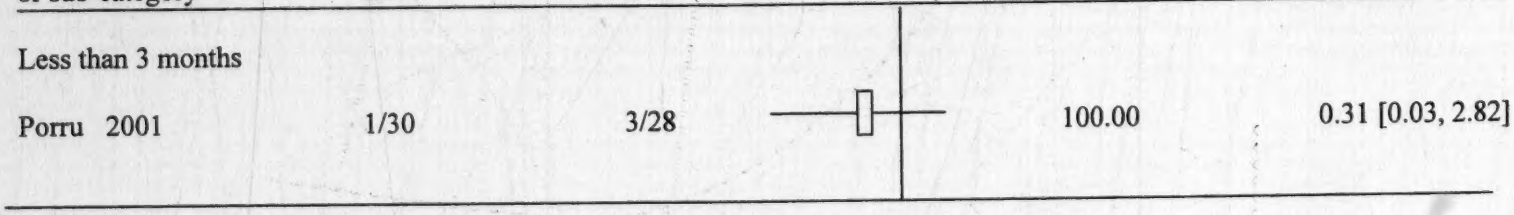


Figure 3-2. Post-operative RP PFMT vs no treatment or placebo or sham (number not cured)

Study or sub category	PMFT n/N	Control n/N	RR 95% CI	Weight %	RR (fixed) 95% CI
Less than 3 months					
Moore 1999	12/18	14/21		9.11	1.00 [0.64, 1.56]
Filocamo 2005	115/150	129/150		90.89	0.89 [0.80, 0.99]
Subtotal	168	171		100.00	0.90 [0.81, 1.00]
Within 3-6 months					
Moore 1999	8/18	7/21		4.93	1.33 [0.60, 2.95]
Dubbleman 2004	21/31	23/32		17.27	0.94 [0.68, 1.31]
Filocamo 2005	35/150	102/150		77.81	0.34 [0.25, 0.47]
Subtotal	199	203		100.00	0.50 [0.40, 0.62]
Within 6-12 months					
Filocamo 2005	16/150	47/150		100.00	0.34 [0.20, 0.57]
Subtotal	150	150		100.00	0.34 [0.20, 0.57]

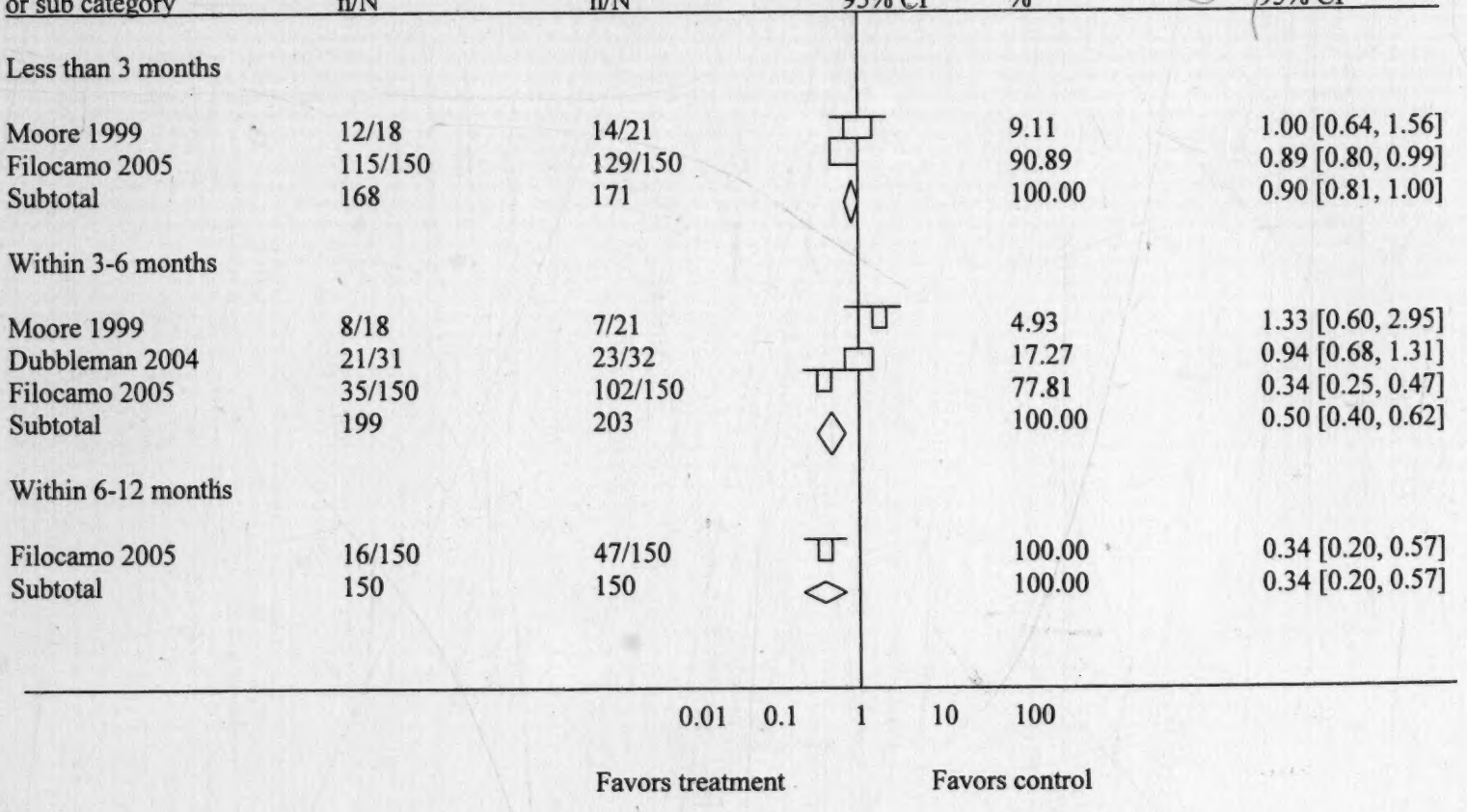


Figure 3-3. Post-operative RP PFMT vs no treatment or placebo or sham (number not improved)

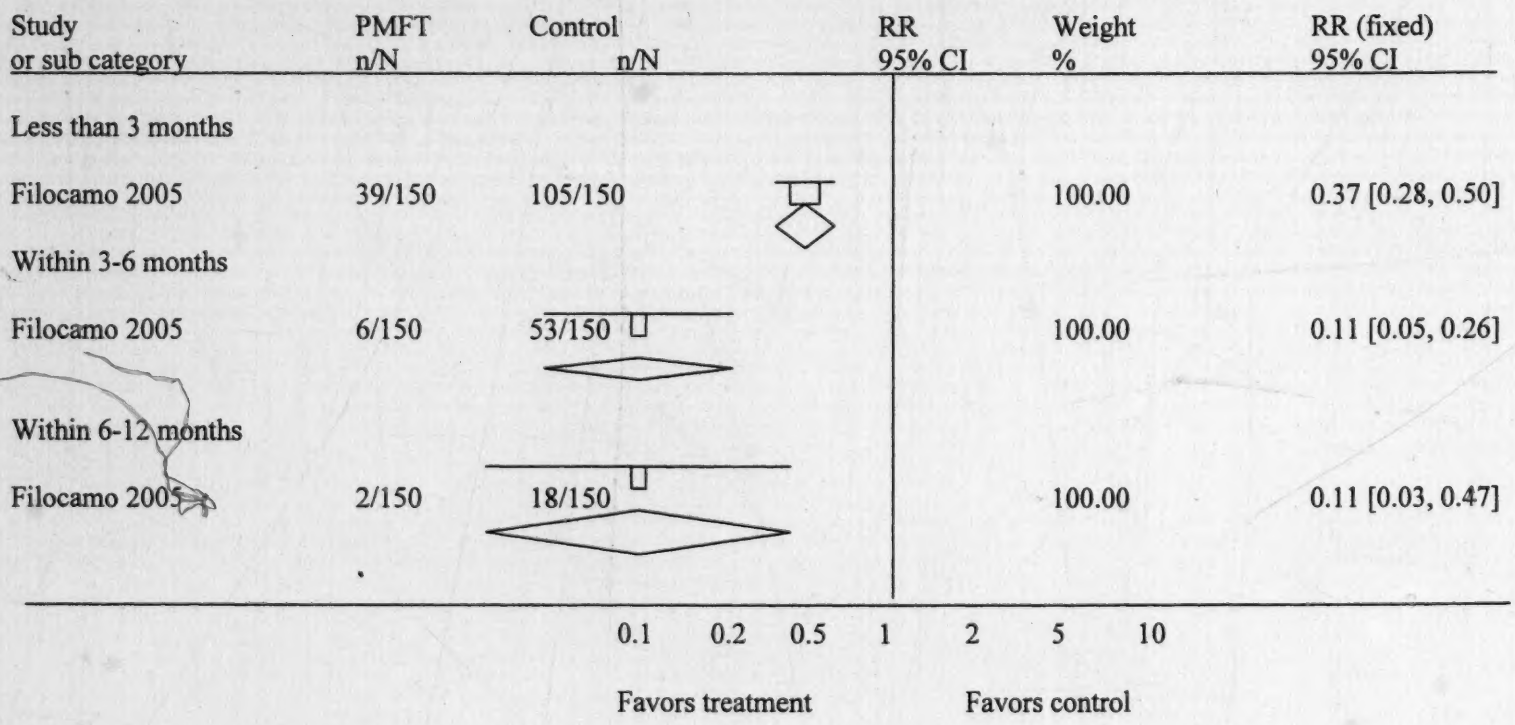


Figure 3-4. Post-operative RP PFMT vs no treatment or placebo or sham (24 hour pad test, grams of urine lost)

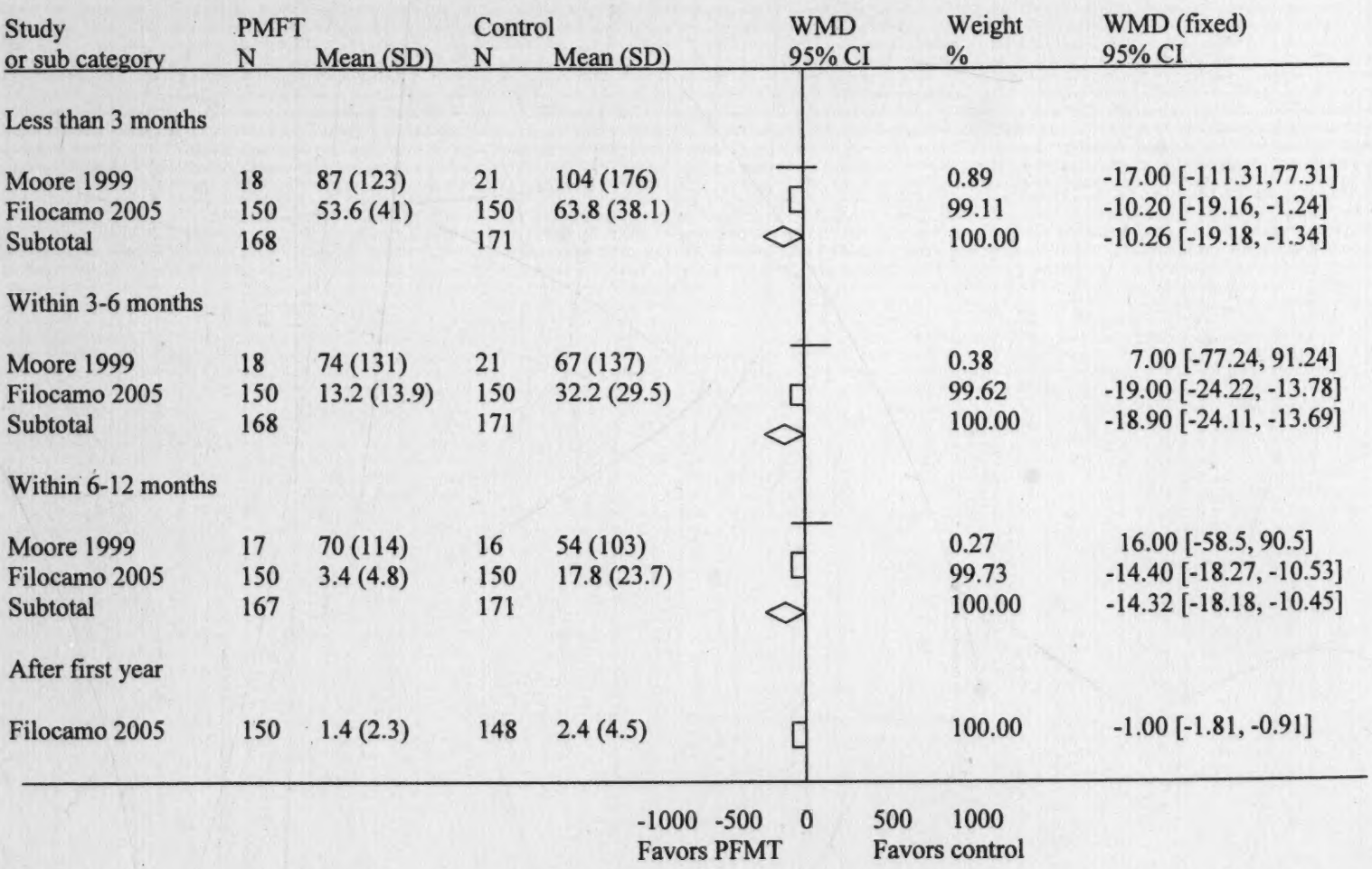


Figure 3-5. Pre-operative RP PFMT + biofeedback vs no treatment or placebo or sham (number not cured)

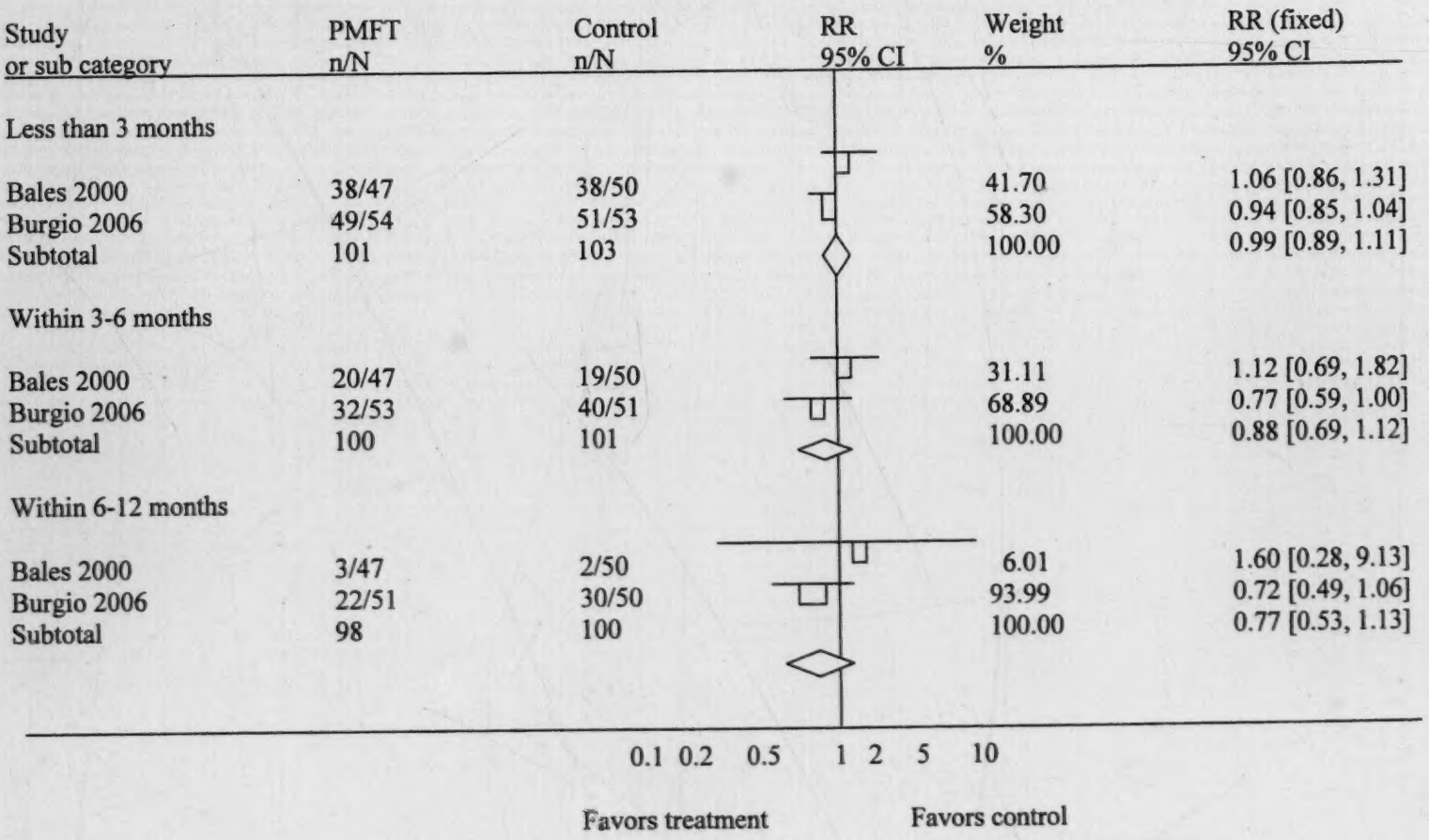


Figure 3-6. Pre and post-operative RP PFMT + biofeedback vs no treatment or placebo or sham (number not cured)

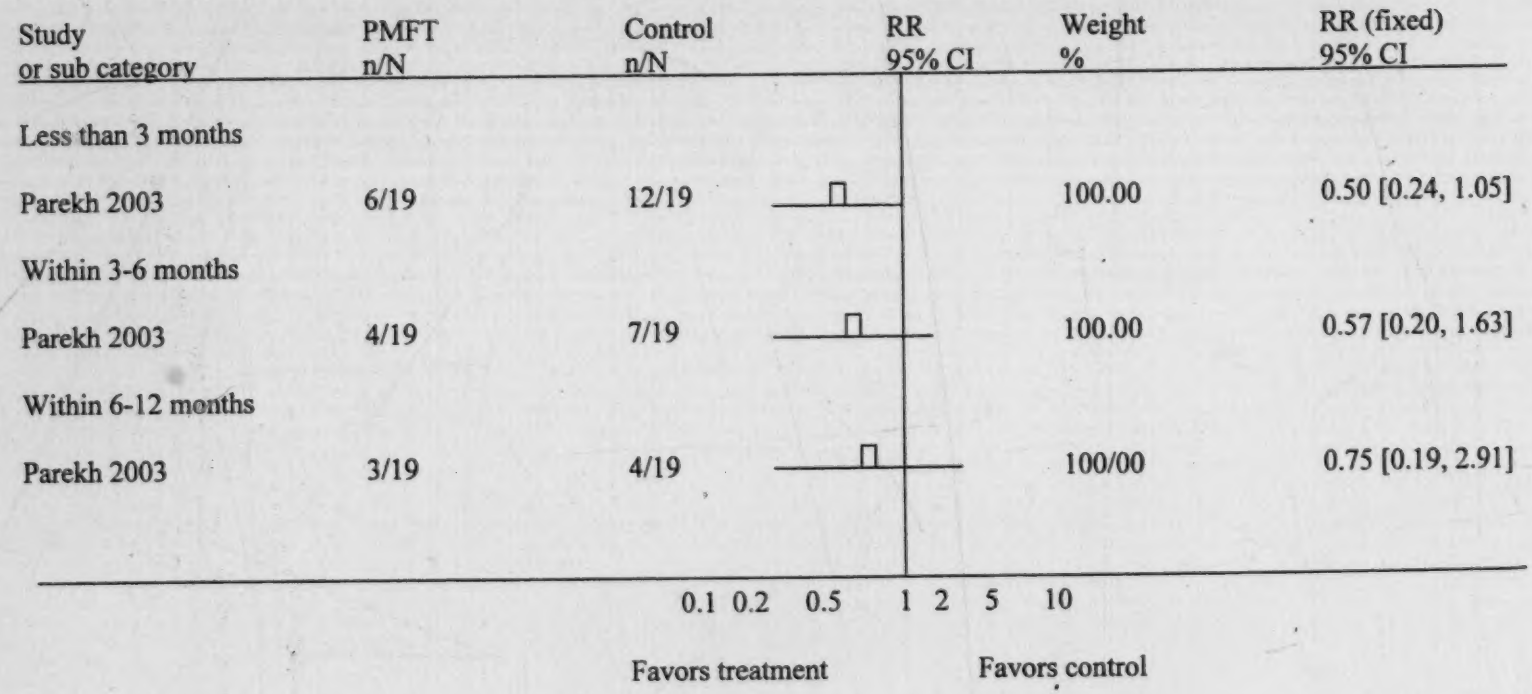


Figure 3-7. Post-operative RP PFMT + biofeedback vs no treatment or placebo or sham (number not cured)

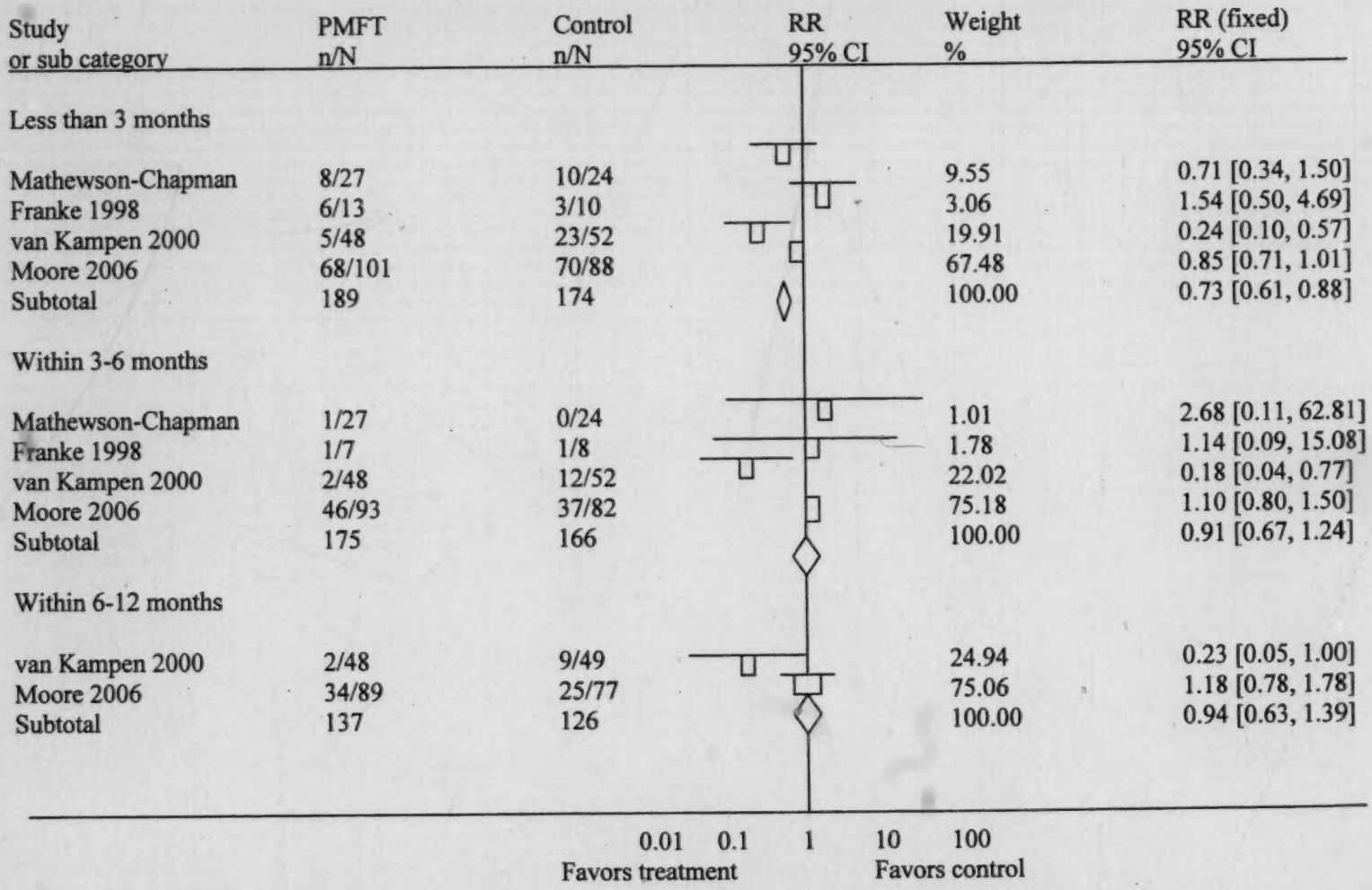


Figure 3-8. Post-operative RP PFMT + biofeedback vs no treatment or placebo or sham (Pad changes over 24 hours)

Study or sub category	PMFT N	Mean (SD)	Control N	Mean (SD)	WMD 95% CI	Weight %	WMD (fixed) 95% CI
Less than 3 months							
Mathewson-Chapman	27	1.1 (2.1)	24	2.04 (2.7)		100.00	-0.94 [-2.28, 0.40]
Within 3-6 months							
Mathewson-Chapman	27	0.6 (1.6)	24	1.80 (2.7)		100.00	-1.20[-2.44, 0.04]

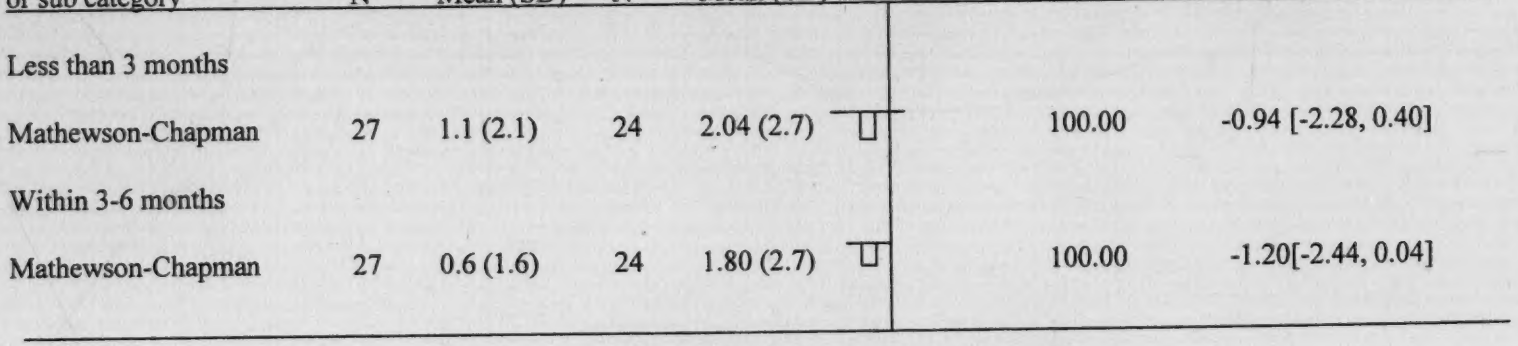


Figure 3-9. Post-operative RP PFMT + biofeedback vs no treatment or placebo or sham (24 hour pad test, grams of urine lost)

Study or sub category	PMFT N	PMFT Mean (SD)	Control N	Control Mean (SD)	WMD 95% CI	Weight %	WMD (fixed) 95% CI
Less than 3 months							
Mathewson-Chapman	27	120.4 (249.2)	24	126 (215.6)		20.99	-5.60 [-133.18,121.98]
Moore 2006	93	114.8 (299.8)	82	71.4 (114.2)		79.01	43.40 [-22.35, 109.15]
Subtotal	120		106			100.00	33.12 [-24.33, 91.56]
Within 3-6 months							
Moore 2006	87	44.7 (141.7)	74	34.9 (100.9)		100.00	9.80 [-27.82, 47.42]
Within 6-12 months							
Moore 2006	89	46.48 (214.6)	77	8.56 (9.69)		100.00	37.92 [-6.72, 82.56]

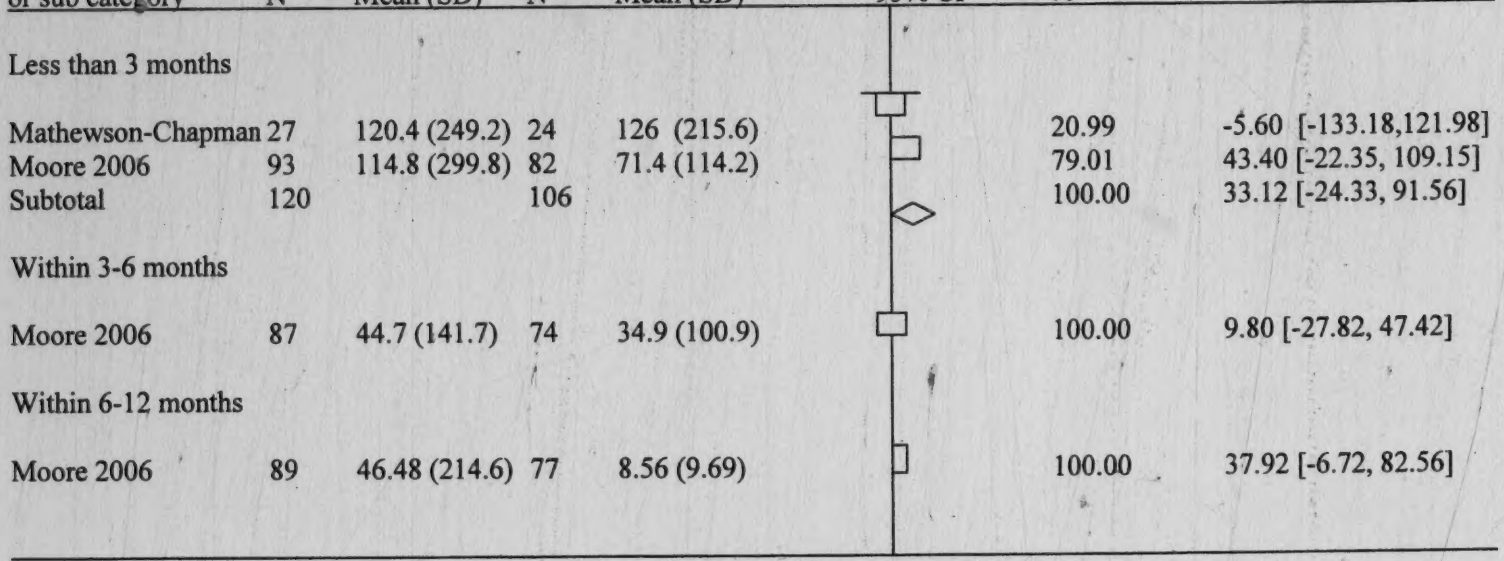


Figure 3-10. Post-operative RP PFMT + biofeedback vs no treatment or placebo or sham (Incontinence episodes over 24 hours)

Study or sub category	PMFT+BF N	Mean (SD)	Control N	Mean (SD)	WMD 95% CI	Weight %	WMD (fixed) 95% CI
Less than 3 months							
Mathewson-Chapman	27	1.5 (3.2)	24	5.6 (20.4)		100.00	-4.10 [-12.35, 4.15]
Within 3-6 months							
Mathewson-Chapman	27	0.84 (1.99)	24	1.00 (0.27)		100.00	-0.16[-0.92, 0.60]

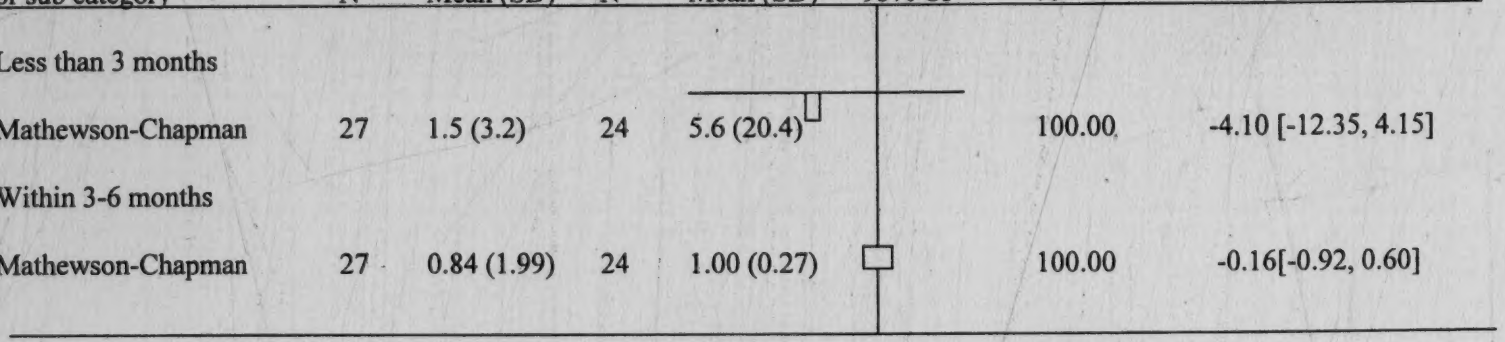


Figure 3-11. Post-operative RP PFMT + biofeedback vs PFMT alone (24 hour pad test, grams of urine lost)

Study or sub category	PMFT N	PMFT Mean (SD)	Control N	Control Mean (SD)	WMD 95% CI	Weight %	WMD (fixed) 95% CI
Less than 3 months							
Floratos 2002	28	6.5 (11.4)	14	3.0 (4.1)		99.70	3.50 [-1.24, 8.24]
Joseph 2000	6	58.66 (97.9)	5	30.5 (40.71)		0.30	28.16 [-57.92, 114.24]
Subtotal	34		19			100.00	3.57 [-1.16, 8.30]
Within 3-6 months							
Floratos 2002	28	3.7 (9.9)	14	1.3 (2.4)		100.00	2.40 [-1.48, 6.28]
Joseph 2000	5	4.4 (6.26)	4	0.0 (0.0)			Not estimable
Subtotal	33		18			100.00	2.40 [-1.48, 6.28]
Within 6-12 months							
Floratos 2002	28	3.10 (8.10)	14	0.0 (0.0)			Not estimable
Joseph 2000	4	6.25 (9.46)	3	0.0 (0.0)			Not estimable
Subtotal	32		17				Not estimable

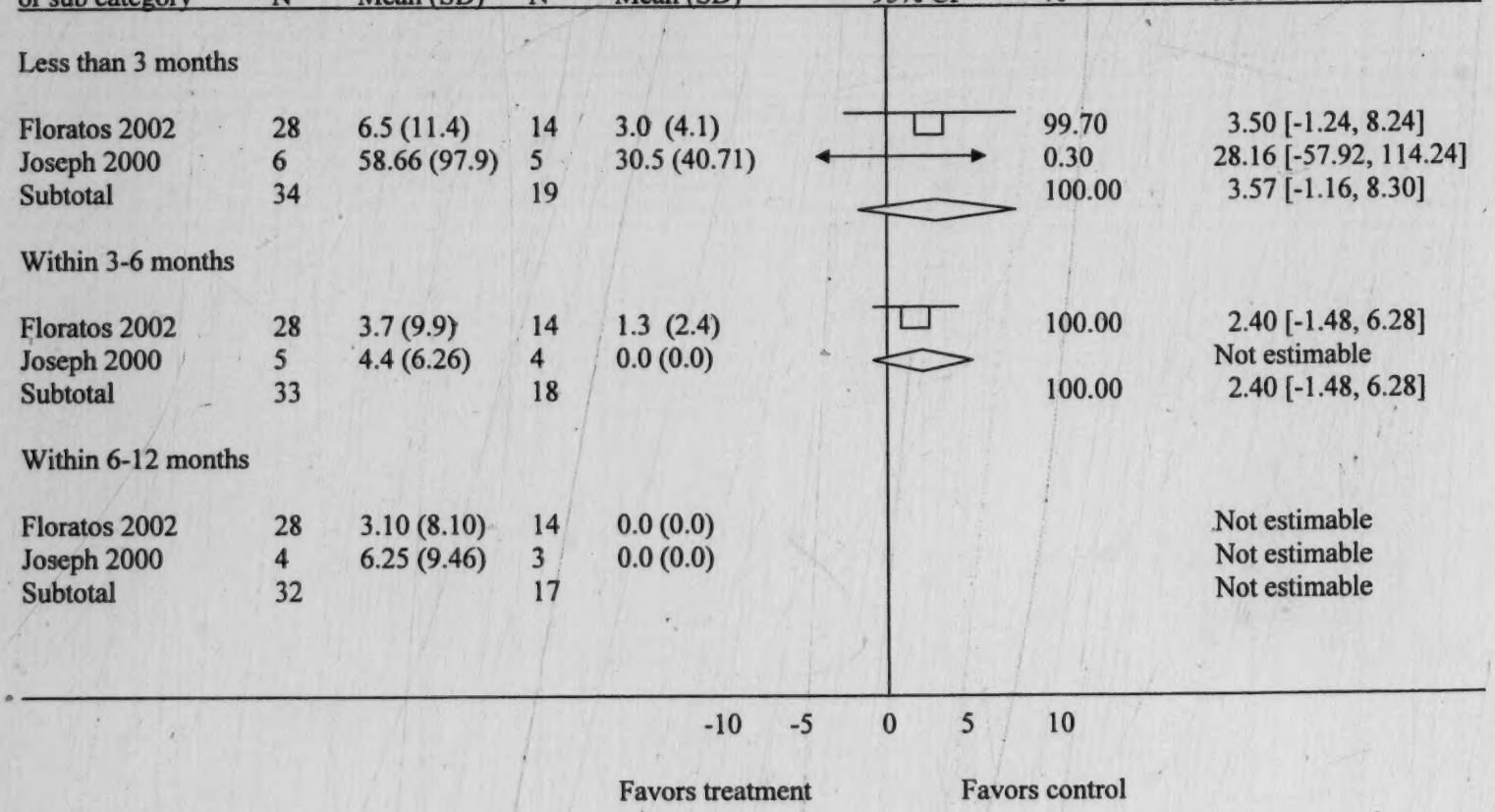


Figure 3-12. Post-operative RP PFMT + biofeedback vs PFMT alone (Pad changes over 24 hours)

Study or sub category	PMFT N	PMFT Mean (SD)	Control N	Control Mean (SD)	WMD 95% CI	Weight %	WMD (fixed) 95% CI
Less than 3 months							
Floratos 2002	28	1.20 (1.10)	14	0.90 (1.00)		100.00	0.30 [-0.36, 0.96]
Within 3-6 months							
Floratos 2002	28	0.80 (1.00)	14	0.40 (0.50)		100.00	0.40 [-0.05, 0.85]
Within 3-6 months							
Floratos 2002	28	0.40 (0.70)	14	0.20 (0.40)		100.00	0.20 [-0.13, 0.53]

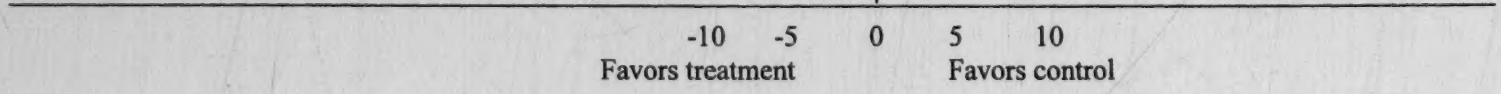


Figure 3-13. Post-operative RP PFMT + anal stimulation vs no treatment or placebo or sham (number not cured)

Study or sub category	PMFT+anal E stim n/N	Control n/N	RR 95% CI	Weight %	RR (fixed) 95% CI
Less than 3 months					
Moore 1999	11/19	14/21		100.00	0.87 [0.53, 1.42]

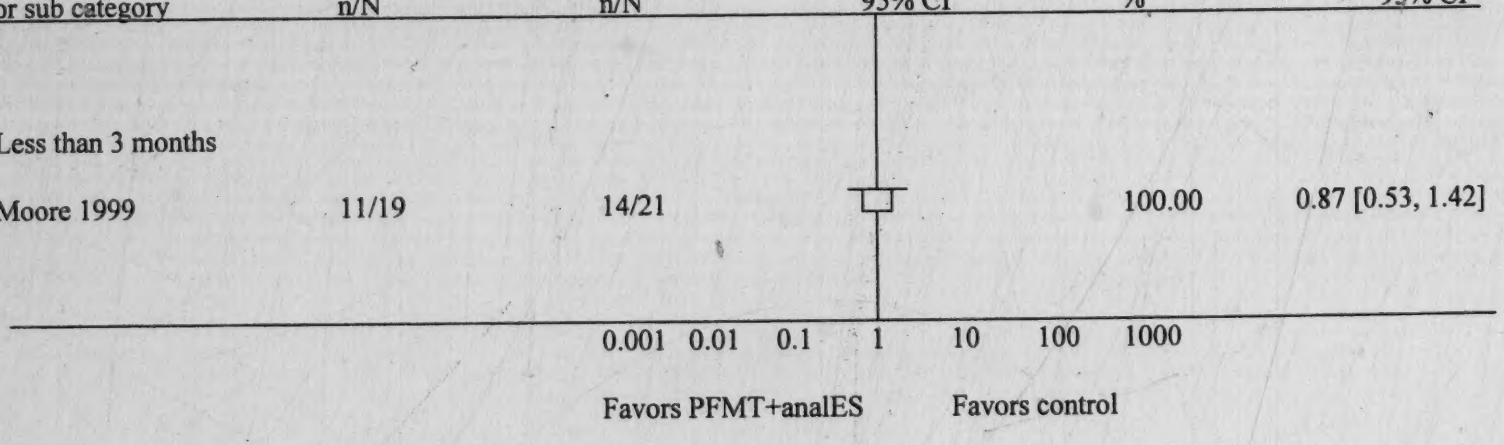


Figure 3-14. Post-operative RP PFMT + anal E stim vs no treatment or placebo or sham (24 hour pad test, grams of urine lost)

Study 4 or sub category	PFMT+anal Estim N	Mean (SD)	Control N	Mean (SD)	WMD 95% CI	Weight %	WMD (fixed) 95% CI
Less than 3 months							
Moore 1999	19	156 (168)	21	104 (176)		100.00	52 [-54.64, 158.64]
Within 3-6 months							
Moore 1999	19	202 (242)	21	67 (137)		100.00	135 [11.41, 258.59]
Within 3-6 months							
Moore 1999	19	98 (132)	14	54 (103)		100.00	44.00 [-29.92, 117.92]

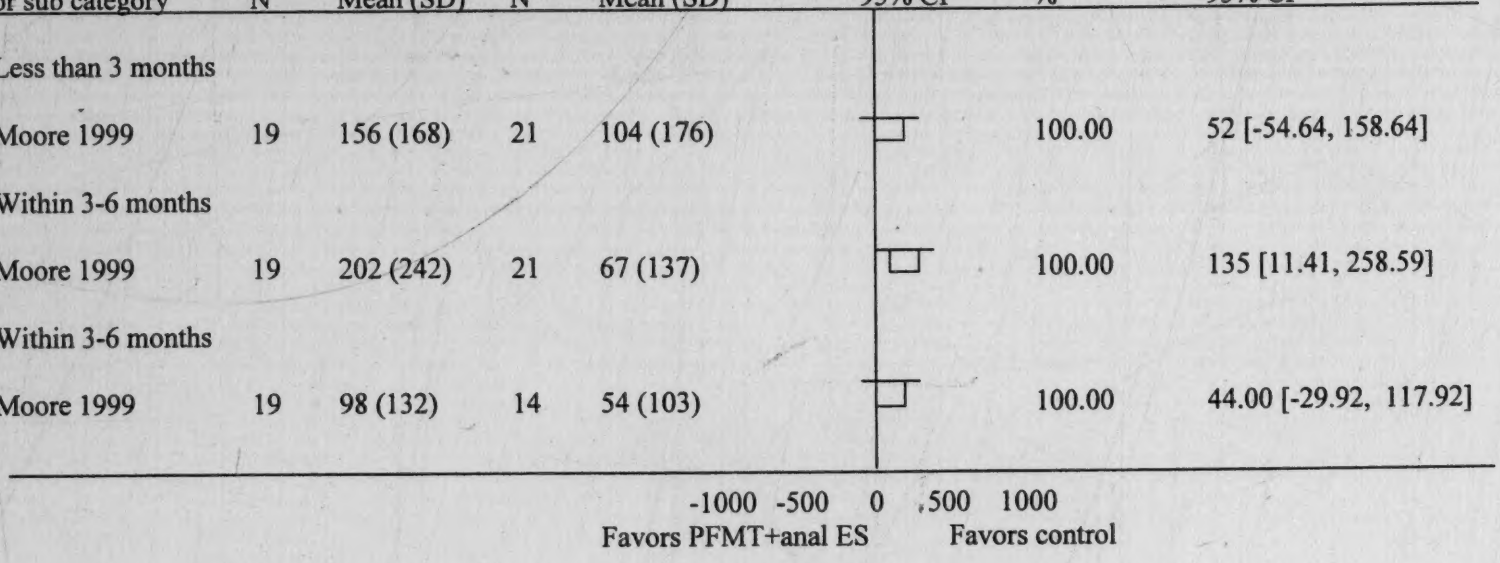


Figure 3-15. Post-operative RP PFMT + anal E stimulation vs PFMT alone (number not cured)

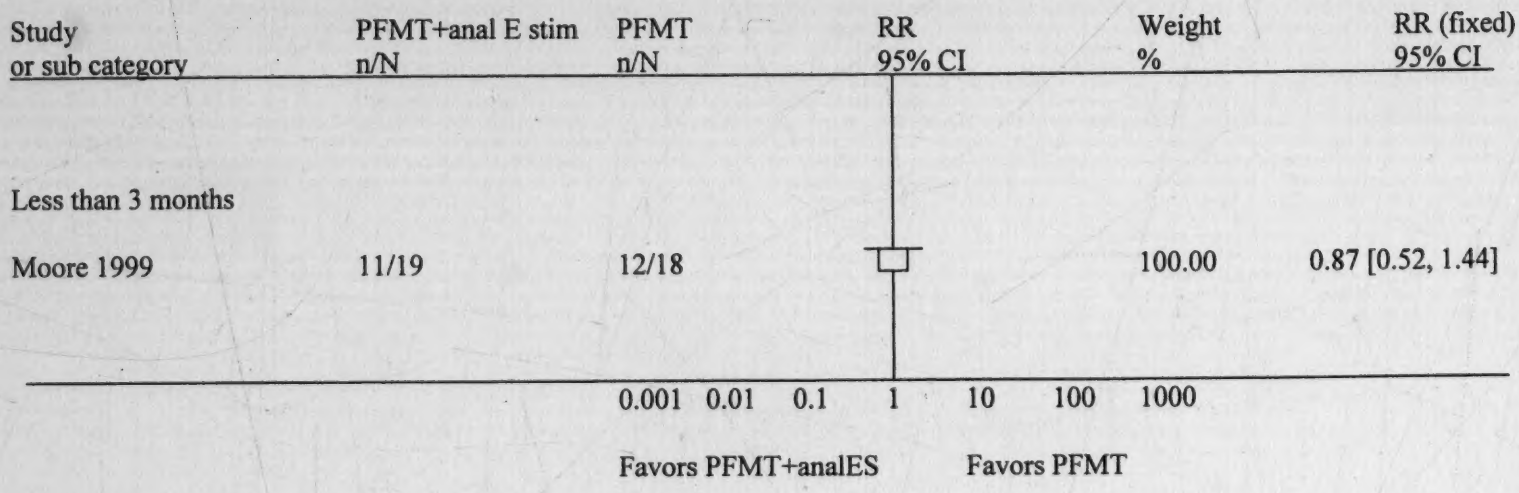


Figure 3-16. Post-operative RP PFMT + anal E stim vs PFMT alone (20 minute pad test, grams of urine lost)

Study or sub category	PMFT+anal Estim N	Mean (SD)	PFMT N	Mean (SD)	WMD 95% CI	Weight %	WMD (fixed) 95% CI
Within 3-6 months							
Wille 2003	26	4.70 (10.00)	27	9.74 (22.10)		100.00	-5.04 [-14.22, 4.14]
Within 6-12 months							
Wille 2003	39	0.39 (0.50)	41	3.70 (9.00)		100.00	-3.31 [-6.07, -0.55]

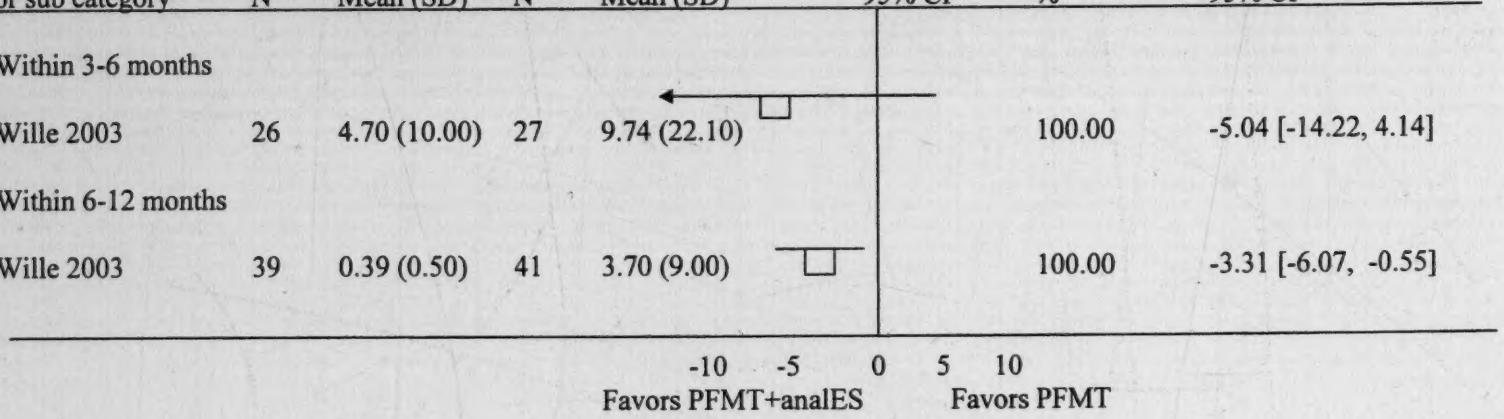


Figure 3-17. Post-operative RP PFMT + anal E stim vs PFMT alone (1 hour pad test, grams of urine lost)

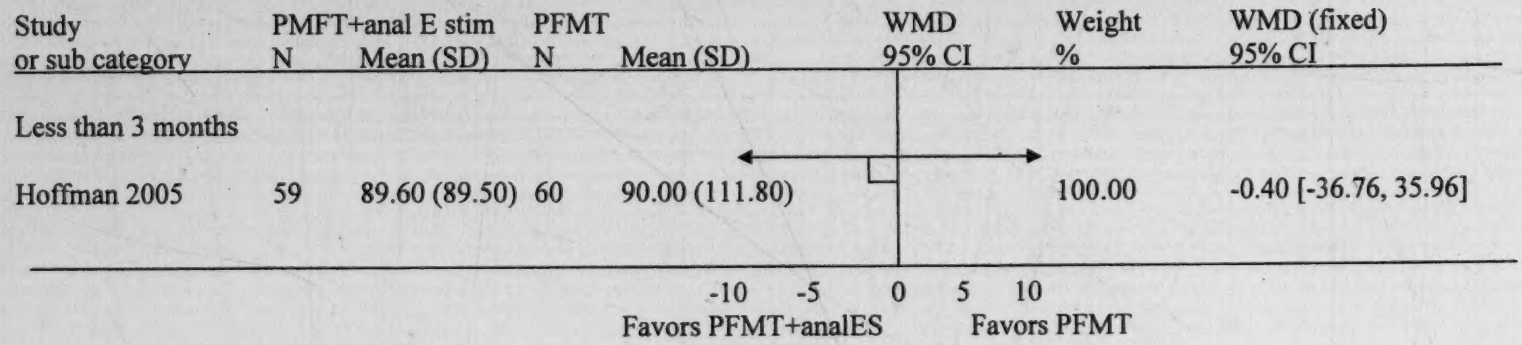


Figure 3-18. Post-operative RP PFMT + anal E stim vs PFMT alone (24 hour pad test, grams of urine lost)

Study or sub category	PMFT+anal Estim N	Mean (SD)	PFMT N	Mean (SD)	WMD 95% CI	Weight %	WMD (fixed) 95% CI
Less than 3 months							
Moore 1999	19	156 (168)	18	87(123)		100.00	69 [-25.53, 163.53]
Within 3-6 months							
Moore 1999	19	202 (242)	18	74 (131)		100.00	128 [3.49, 252.51]
Within 3-6 months							
Moore 1999	19	98 (132)	17	70 (114)		100.00	28 [-52.37, 108.37]

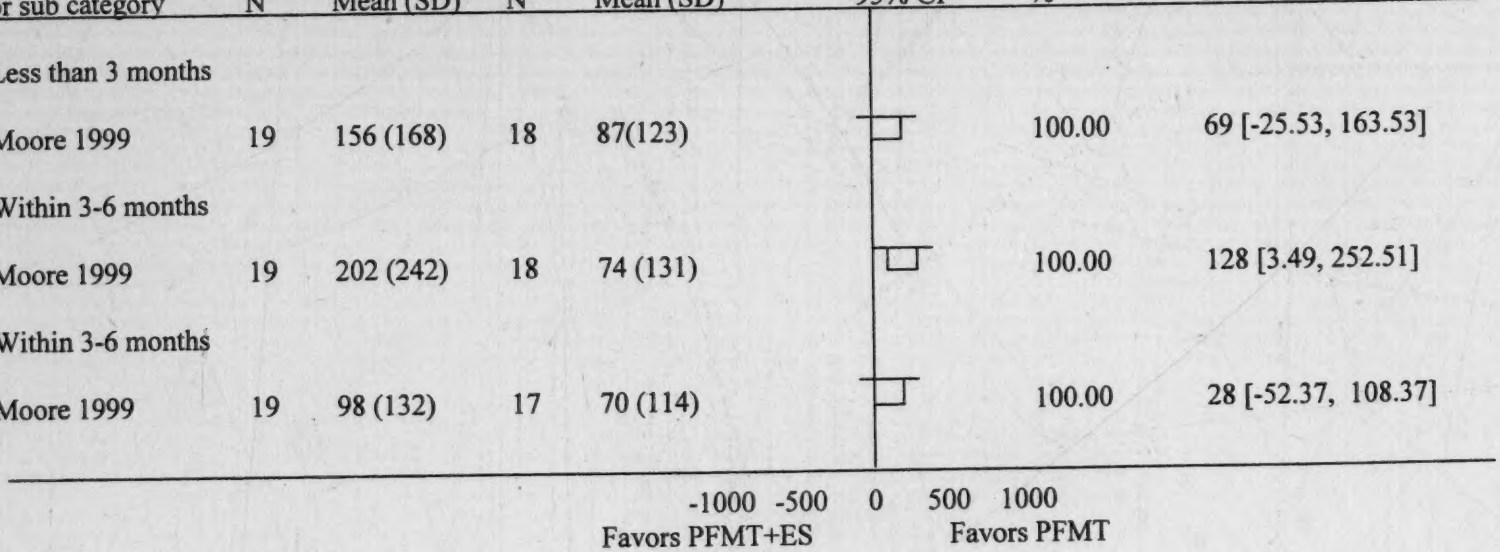


Figure 3-19. Post-operative RP PFMT + perineal E stim vs PFMT alone (1 hour pad test, grams of urine lost)

Study or sub category	PMFT+perinealEstim N	Mean (SD)	PFMT N	Mean (SD)	WMD 95% CI	Weight %	WMD (fixed) 95% CI
Less than 3 months							
Hoffman 2005	59	85.30 (89.50)	60	90.00 (111.80)		100.00	-4.70 [-42.90, 335.50]

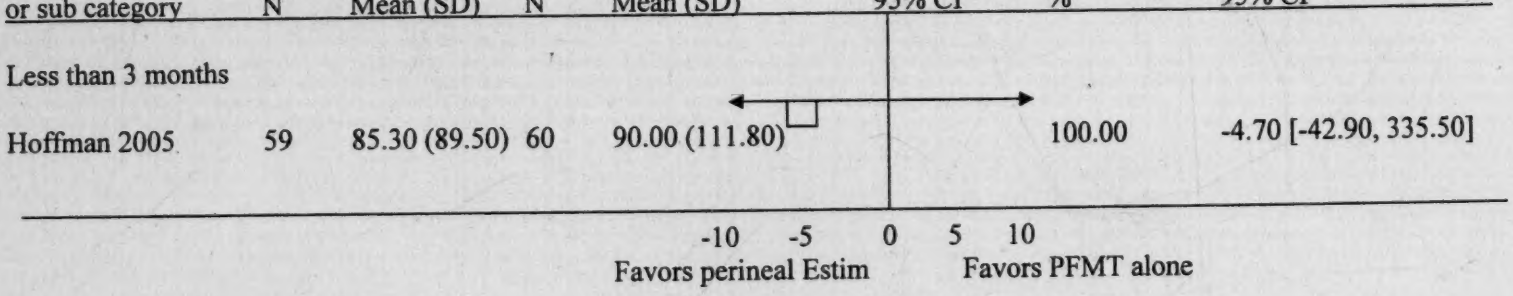


Figure 3-20. Post-operative RP PFMT + anal E stimulation + biofeedback vs no treatment or placebo or sham (number not cured)

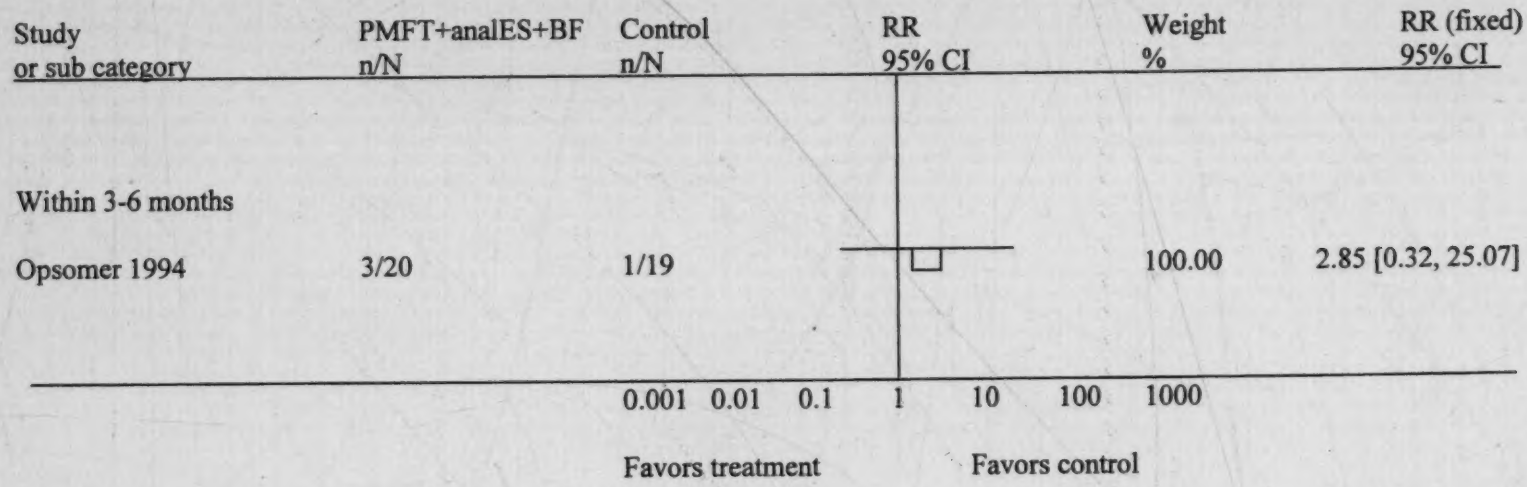


Figure 3-21. Post-operative RP PFMT + anal E stim + biofeedback vs PFMT alone (20 minute pad test, grams of urine lost)

Study or sub category	PMFT+anal Estim N	Mean (SD)	PFMT N	Mean (SD)	WMD 95% CI	Weight %	WMD (fixed) 95% CI
Within 3-6 months							
Wille 2003	26	4.45 (12.40)	27	9.74 (22.10)		100.00	-5.29 [-14.89, 4.31]
Within 6-12 months							
Wille 2003	44	0.43 (0.66)	41	3.70 (9.00)		100.00	-3.27 [-6.03, -0.51]

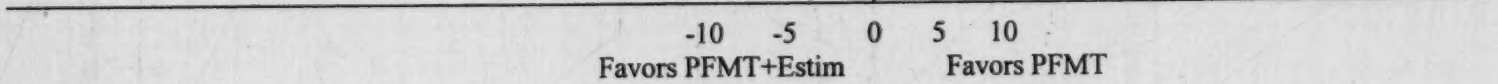
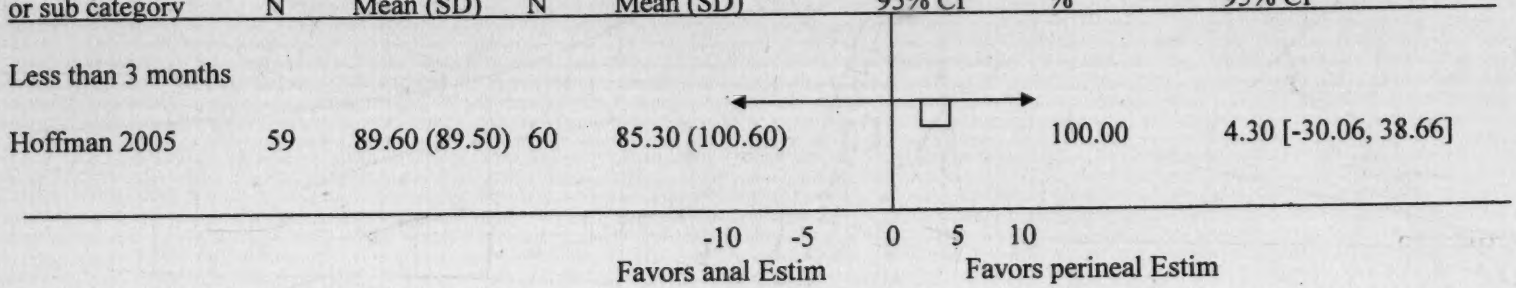


Figure 3-22. Post-operative RP anal E stim vs perineal E stim (1 hour pad test, grams of urine lost)

Study or sub category	PMFT+anal Estim N	Mean (SD)	PFMT +Perineal E Stim N	Mean (SD)	WMD 95% CI	Weight %	WMD (fixed) 95% CI
Less than 3 months							
Hoffman 2005	59	89.60 (89.50)	60	85.30 (100.60)		100.00	4.30 [-30.06, 38.66]



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CHAPTER 4

Paper 3: Pharmacotherapeutics in Older Adults[1]

Footnote:

[1]A version of this chapter has been accepted for publication

Hunter, K.F. & Cyr, D. (in press). Pharmacotherapeutics in older adults. *JWOCN: Journal of Wound, Ostomy and Continence Nursing*

Mr. Z. is an 84 year old male in hospital for a fractured hip. His previous health history includes congestive heart failure, hypertension and early stage dementia. Medications include: lisinopril, hydrochlorothiazide and metoprolol. Prior to surgery, he had been living at home with his wife and was still independent in most activities of daily living. Post-operatively, he has been restless, more confused and hallucinating. Medications added to his profile postoperatively include meperidine, dimenhydrinate and haloperidol 5 mg prn.

Mr. Z is likely in a post-operative delirium. In cases such as these we need to consider the following questions:

- *What medication changes/additions have been made?*
- *What are potential side effects of these medications?*
- *Are the doses appropriate for an older person?*
- *Are the drugs appropriate for an older person?*
- *Are the drugs appropriate for this person's health history?*

The combined effects of aging, chronic disease management, and medication use in older adults creates highly complex care issues for the client and his or her health care team. In this paper, the influence of the aging process on how drugs affect the body and how the body affects drug absorption, distribution, metabolism and excretion will be reviewed. Side effect profiles and specific drug groups of concern are discussed in terms of drug induced geriatric syndromes. Concerns of older adults, including medication adherence and challenges of balancing medication use in multiple chronic or acute illnesses, will be explored.

Aging versus Disease

Age changes alter pharmacokinetics and pharmacodynamics, leaving implications for practitioners to be aware of regarding drug dosing and alterations in drug response. Additionally, chronic illnesses become more prevalent with age. Multiple disease states can also affect medication use and response. The person with comorbid chronic illnesses is more likely to be on multiple medications, increasing the chance for drug-drug interactions.

Pharmacokinetic Changes

Pharmacokinetics is the medical description of the absorption, distribution, biotransformation (metabolism), and excretion of drugs and their metabolites (Holford, 2001). In other words, it describes the movement of drugs through the body over time. Each of these processes can be affected by aging, and by the presence of disease.

Absorption is the rate and extent at which a drug leaves the site of administration and moves into the blood. Age changes that affect absorption include a decreased intestinal blood flow, and slowing of gastrointestinal motility. Interestingly, the slowed motility may compensate for decreased blood flow, as food and drugs stay in the gut longer, increasing the time for absorption. In older adults, changes in absorption are more likely caused by disease than aging. Additionally, consumption of non prescription drugs may alter absorption. For example, antacids and laxatives may alter absorption by binding with the medications or decreasing length of time they are in the gut.

Distribution occurs when the drug reaches circulation, at which time it must penetrate the tissues to act. This can be affected by health status (e.g. circulation), cell transport (entering, receptor binding), plasma protein binding capacity, and lipid versus

water solubility. Age changes which affect distribution include a decrease in total body mass, total body water and lean body mass (Katzung, 2001). Body fat increases, while total plasma albumin may decline. The blood-brain barrier is thought to become less effective with age. Disease can also cause a decrease in albumin if nutritional status becomes more at risk, and impaired circulation means poor penetration of medications into the tissues. Results of changes related to aging and disease can mean that highly fat soluble drugs, such as some benzodiazepines (Katzung, 2001), have increased volume of distribution as well as prolonged distribution, half life, and duration of action. Altered protein binding of some drugs (altered ratio of bound:free drug) results in more intense effects. Alternately, there will be less intense effect in areas with reduced circulation.

Health science researchers are learning more about some of the complex phases of biotransformation/metabolism. Phase I reactions in this process include oxidation, reduction and hydrolysis. During oxidation, drugs are catalysed by enzymes which are called mixed function oxidases, the cytochrome P-450 (CYP-450) system (Correia, 2001). During Phase II, drugs are conjugated with endogenous compounds making the drug more hydrophilic, so it can be excreted via the renal system. Drugs, and even some foods, can be inducers or inhibitors of the CYP-450 enzyme system (Correia, 2001; Mycek, Harvey, & Champe, 2000). Grapefruit juice is one example of a food that can affect the bioavailability of some drugs (Veronese et al., 2003). Inducers increase the activity of an isoenzyme of the system. The increased rate of metabolism leads to a decline in circulating drug. Inhibitors decrease activity of the system, leading to a decreased rate of metabolism and a subsequent rise in amount of circulating drug. See Table 4-1 for further illustration of the CYP-450 system in older adults.

Renal excretion is responsible for most drug elimination from the body (Mycek et al., 2000), favoring excretion of water soluble drugs or metabolites. Drugs that remain lipid soluble after metabolism are more readily reabsorbed in the renal tubules, extending drug action. Renal efficiency is decreased with aging resulting in a decline in glomerular filtration rate and in serum creatinine clearance. In older adults, serum creatinine levels remain within the same reference ranges as younger adults even though kidney function declines. As serum creatinine is a muscle breakdown product, the lower muscle mass of seniors results in lower production of creatinine. Hence there is less creatinine to excrete, keeping serum levels the same despite the decline in clearance (Katzung, 2001). Other changes of aging which may alter drug excretion are a decline in thirst awareness, which increases risk of dehydration and further compromises filtration rate. A decline in respiratory capacity reduces release of drugs excreted through expiration.

Pharmacodynamic Changes

Pharmacodynamics can be thought of as the effect of the drug on the body. With aging, there is a change in number and affinity of drug receptor sites on cell walls (Katzung, 2001). Additionally, the blood-brain barrier allows more drug to cross into the central nervous system. Other aging changes include a decline in the availability of some neurotransmitters, the messenger chemicals in the nervous system (Raz, 2000). For example, acetylcholine is known to decline with the aging process.

Disease effects which compound these changes of aging relate to the loss of specific neurotransmitters. In some dementias, notably Alzheimers and Lewy body dementias, there is a profound additional loss of acetylcholine. In Parkinson's disease, the neurotransmitter decline is in dopamine. This produces concern about use of drugs with

anticholinergic or extrapyramidal effects or side effect profiles. Use of anticholinergics, which can cause dry mouth, urinary retention and confusion, can further increase risk of geriatric syndromes such as impaired cognition and urinary retention with overflow incontinence (Broadhurst, Wilson, Kinirons, Wagg, & Dhesi, 2003). Drugs with extrapyramidal effects can produce parkinsonian like symptoms of rigidity, bradykinesia and akathisia (motor restlessness).

Side Effect Profiles and Drug Classes of Concern in Older Adults

Any drug has potential side effects or adverse effects, but there are some drug classes, commonly prescribed to or used by seniors, that have specific effects of concern. For example, as reviewed above, drugs with anticholinergic and extrapyramidal effects lead to the onset or exacerbation of geriatric syndromes. Geriatric syndromes include falls, incontinence, confusion and mobility/functional changes (Resnick, 2003). In Table 4-2, a summary of classes of drugs with potential adverse effects and associated geriatric syndromes is outlined.

Drugs with Anticholinergic Effects.

Drugs with anticholinergic effects include the anticholinergic agents used for detrusor (bladder) overactivity, antipsychotics, tricyclic antidepressants, antiemetics and antihistamine agents (Fonda, 2002). In recent years, many other agents have been identified as having anticholinergic side effects (Tune, 2001). Geriatric syndromes that may result from the adminstration of anticholinergics include urinary retention and acute confusion (delirium). Risk of urinary retention is increased, and groups predisposed to retention, such as older males who have underlying benign prostatic hypertrophy, should be monitored. Some agents, notably diphenhydramine, have been found to increase risk

of delirium and the need for urinary catheterization to treat retention in older adults (Agostini, Leo-Summers, & Inouye, 2001). Anticholinergic effects of antihistamines and tricyclic antidepressants can also worsen glaucoma and cause blurred vision. Concomitant side effect profiles of concern are the alpha adrenergic blockade with tricyclic antidepressants (Mycek et al., 2000), increasing risk of postural hypotension and the extrapyramidal side effects of antipsychotics (Mycek et al., 2000) resulting from the dopamine blockade.

Benzodiazepines

Benzodiazepines act on the central nervous system, and have been found to be related to increased fall risk in older adults (de Rekeneire et al., 2003; Tromp et al., 2001). An additional concern with benzodiazepines are that lipid soluble drugs in this group have an extended action due to slow excretion. Long acting benzodiazepines in particular cause prolong sedation and increase risk of falls in older adults (Fick et al., 2003). Long time users must be weaned off slowly to avoid withdrawal symptoms, as addiction can occur. Benzodiazepines should be used with great caution in the older population and should never be used on a long term basis.

Diuretics

There are several different classes of diuretics, with varying potencies. The loop diuretics are among the most potent. The most well known agent in this class is furosemide. In general, the risk of using diuretics in older individuals is the depletion of electrolytes (e.g. potassium, sodium) and dehydration. This can lead to acute renal failure. Falls and increased confusion are frequently part of an altered presentation of illness, including dehydration, in the elderly. Urinary incontinence from increased urine

output and frequency can also occur with diuretic use. Urinary incontinence has been associated with an increase risk of falls (de Rekeneire et al., 2003; Kron, Loy, Sturm, Nikolaus, & Becker, 2003; Tromp et al., 2001).

Narcotic analgesics

Any narcotic analgesic can have the side effects of sedation and constipation. However, there are some agents in this group that have more pronounced risk of these in older adults. Meperidine is metabolized to normeperidine, which is excreted by the kidney. The elderly are not as efficient at excreting this metabolite and so it accumulates more readily. Unfortunately, it also crosses the blood brain barrier where it can induce delirium and, in rare cases, seizures. It has been associated with the development of delirium in older adult hip fracture patients (Adunsky, Levy, Heim, Mizrahi, & Arad, 2002; Morrison et al., 2003) and is best avoided altogether in older adults. Codeine may cause more constipation for the amount of analgesia it gives. One study of older cancer patients found that lower doses or weaker opiods were just as likely to cause constipation as high dose opiods (Bennett & Cresswell, 2003). This can be problematic in the older population. Another study found equal pain relief for with less constipation in people with chronic low back and osteoarthritic pain on an acetaminophen/non-narcotic analgesic versus an acetaminophen/codeine combination (Mullican & Lacy, 2001). Propoxyphene, although it is a narcotic with all the disadvantages and side effects of narcotic agents (including addiction), may not be any more effective for pain control than plain acetaminophen (MICROMEDEX Healthcare Series). To avoid narcotic related side effects in older adults, consideration should be given to trying a regime of regular dosing of acetaminophen as an alternative to narcotics.

NSAIDS

Non-steroidal anti-inflammatory agents (NSAIDS) can be effective in management of inflammation and pain, and are useful adjuncts and replacements for narcotics. However, we need to use caution when using these agents in the older population. NSAIDS decrease renal blood flow, increase blood pressure and can put patients into acute renal failure (Gambaro & Perazella, 2003). For patients who have congestive heart failure (CHF) or hypertension, NSAIDS may exacerbate their condition. Additionally, NSAIDS inhibit prostaglandin production, which protects the gastrointestinal (GI) tract, chronic use can lead to ulcerations of the GI tract and GI bleeds (Stringer, 2001). The COX II inhibitors are thought to lower this risk, as they do not inhibit GI prostaglandin production to the same degree. The recent withdrawal of rofecoxib from the market due to cardiovascular risk , including stroke and myocardial infarction, indicate GI bleeding was perhaps the least of the concerns with this class of drugs. It will be important to keep current with the new agents in this class, such as valdecoxib. Use of NSAIDS in older adults with chronic cardiovascular history may need to be approached with caution, and may ultimately be contraindicated.

Other Medications

Calcium channel blockers have been identified as a potential suppressant of bladder (detrusor) activity (Wagg & Cohen, 2002) as there is a theoretical effect of decreasing smooth muscle activity. Early animal studies showed some effect of calcium channel blockers on hyperactive bladder (Saito & Kondo, 1998; Yu, Wein, & Levin, 1996). However, none of the agents investigated have been marketed as specific agents to

decrease detrusor hyperactivity and risk of urinary retention has not been consistently identified as a side effect.

Challenges for Medication Use in Seniors

Some of the challenges involved in medication management for seniors include dosage adjustment, polypharmacy issues, and adherence to the prescribed routine.

Dose Adjustments

In older adults, the general rule is to "start low and go slow." For some medications, one tenth of the dose is prescribed for an older person than that which is recommended for younger adults. For example, one tenth the usual dose of 5-10 mg. of haloperidol translates into a geriatric dose of 0.5-1mg. Medication doses can also be adjusted by calculating the creatinine clearance rate and determining the dose based on this calculation (Katzung, 2001). Consult your team pharmacist or a resource with geriatric dosing issues. The pharmacist is an important team member for the nurse to liaise with, as he or she can help navigate the many issues regarding renal and hepatic function, altered body composition and potential neurotransmitter effects to determine appropriate dosing for older clients.

Polypharmacy

With increased age comes increased risk of living with one or more chronic illnesses. This places many seniors in a situation of multiple medication use, especially in conditions such as congestive heart failure or diabetes, where combined therapy is used to stabilize disease. For some, polypharmacy should no longer be merely a count of medications, as use of multiple medications to manage chronic conditions is often

indicated (Swift, 2003). It should be remembered that medications may include prescription as well as over the counter (OTC) agents and herbal remedies.

Use of multiple agents becomes problematic when there is not good rationale for their use, when medications are added to counteract side effects or when there is potential for drug-drug, drug-disease, or drug-food interaction.

Adherence

Much discussion has been had on the issue of compliance with medication regimes. Adherence is replacing the concept of "compliance" when discussing medication management, as it infers a less rigid approach to medication management. There is increased awareness that we need to take into account the individuals' health goals, lifestyle and culture preferences in reviewing medication use (Robbins, Rausch, Garcia, & Prestwood, 2004). A structured medication review is an approach to determine if all the medications on board are required and appropriate. This can be undertaken by the physician, nurse, pharmacist with the client, allowing for client input and questions. Medical history and medications are reviewed simultaneously, and medications which are no longer necessary or which require adjustment are identified. This information is taken to the primary prescriber, if they are not doing the review, so that changes can be made.

Strategies to assist clients in medication management include simplifying the regime (e.g. use once daily dosing versus multiples times when possible), use of memory aids such as divided pillboxes (Robbins et al., 2004) or bubble packing medication with days/times for taking indicated or telephone reminder services (Schlenk, Dunbar-Jacob, & Engberg, 2004), and providing simple, clear written instructions (Schlenk et al., 2004) in large font. Additionally, assessing financial barriers to optimum medication use

(Katzung, 2001) and proposing alternatives, such as generic brands, should be addressed. Team work between the client, nurse, physician, pharmacist is crucial in optimal medication management.

What about Mr Z?

- *Change demerol to morphine (2.5 –5 mg prn) or plain acetaminophen (650 mg qid). An NSAID would not be appropriate due to Mr Z's history of CHF and hypertension.*
- *NO acetaminophen with codeine as this medication may worsen confusion and, as well, lead to constipation.*
- *Discontinue the dimenhydrinate due to high anticholinergic side effects. Mr Z is known to have an early dementia, which makes him especially susceptible to anticholinergic effects. If antiemetic needed, use metoclopramide, which has less anticholinergic side effects, but some extrapyramidal side effects. These should not be problematic if only a few doses are required.*
- *Decrease the dose of haloperidol to the geriatric dose, or change to an atypical antipsychotic such as quetiapine which has less anticholinergic and low extrapyramidal side effects.*
- *Monitor response to medications closely, especially when given "prn" for symptom management. Was the expected effect of the medication on the target system observed in Mr Z? Are any side effects present? Discontinue use of analgesics, anti-emetics and antipsychotics as soon as possible.*

Conclusion

Older adults, especially those living with multiple chronic diseases, represent some of the most complex clients to whom nurses provide care. A solid understanding of

how the aging process and disease affect pharmacodynamics and pharmacokinetics in older adults is needed to anticipate potential issues with medications that clients may encounter. A team approach, which includes the patient, pharmacist and family physician as well as the nurse, is an important component of care.

Table 4-1

CYP450 system in older adults

System change	Potential drug action effects
Multiple drugs may be metabolized by the same isoenzyme of the CYP450 system.	Drug effects can either enhanced or reduced. For example, carbamezepine acts as an inducer of the CYP3A4 system, and can decrease activity of other drugs metabolized by this isoenzyme including medications frequently used by seniors including (but not limited to) acetaminophen, diltiazem, lovastatin.
Hepatic metabolism is slowed with aging, decreasing CYP450 activity.	Drug activity may be prolonged.
Disease may cause hepatic function decline (e.g. CHF, malnutrition).	Drug activity may be prolonged.
Some environmental pollutants and foods and act as inducers or inhibitors of the system, affecting the metabolism of drugs and either decreasing or increasing drug action.	Grapefruit juice inhibits intestinal and hepatic CYP 3A4 and may dramatically increase levels of drugs which are substrates for this enzyme. Examples of drugs that seniors may take which are affected include: calcium channel blockers (e.g. nifedipine, felodipine, diltiazem, verapamil) and anticholesterol agents (e.g. lovastatin, atorvastatin, simvastatin).

Table 4-2

Potential medication induced geriatric syndromes in older adults

Drug class	Used in	Examples	Action/Side effects of concern	Potential exacerbation of geriatric syndromes
Tricyclic Antidepressants	Depression	amitriptyline (Elavil) nortriptyline (Aventyl) imipramine (Tofranil)	High in anticholinergic side effects	Bladder/bowel dysfunction: older agents are high in anticholinergic side effects which decrease detrusor contractility and increase risk of urinary retention. Falls: increased risk due to orthostatic hypotension
Anticholinergics	Urge incontinence	oxybutynin (Ditropan) tolterodine (Detrol)	Anticholinergic agents	Bladder/bowel dysfunction: decrease detrusor contractility, may result in urinary retention. Confusion

Drug class	Used in	Examples	Action/Side effects of concern	Potential exacerbation of geriatric syndromes
Histamine antagonists	Motion sickness, nausea Congestion Allergies (many available in over the counter preparations).	(H1) antagonists (first generation) dimenhydrinate (Gravol, Dramamine) diphenhydramine (Benadryl)	Older agents high in anticholinergic side effects	Bladder/bowel dysfunction: outlet obstruction/acute urinary retention and incontinence secondary to drowsiness, sedation. Confusion secondary to sedation.
Benzodiazepines	Anxiety disorders	lorazepam (Ativan) oxazepam (Serax) temazepam (Restoril)	Drowsinesss, diminished motor skill/coordination.	Bladder/bowel dysfunction: incontinence secondary to drowsiness, sedation. Falls: raises risk (sedation, ataxia)

Drug class	Used in	Examples	Action/Side effects of concern	Potential exacerbation of geriatric syndromes
Antipsychotics	Psychosis in psychiatric illness or delirium. BPSD (behaviour and psychological symptoms of dementia).	<u>D2 Antagonist</u> halperidol (Haldol) loxapine (Loxapac) <u>Atypical</u> olanzapine (Zyprexa) risperidone (Risperdal) quetiapine (Seroquel)	Anticholinergic and extrapyramidal side effects. Akathisia	Bladder dysfunction: some agents are high in anticholinergic side effects – may decrease detrusor contractility resulting in urinary retention. Fall risk: increased due to orthostatic hypotension . As well, bradykinesia/rigidity may be worsened in Parkinsons or Lewy body dementia. Confusion: the motor restlessness of akathesia can be mistaken for acute confusion.

Drug class	Used in	Examples	Action/Side effects of concern	Potential exacerbation of geriatric syndromes
Diuretics	Hypertension, management of fluid load in CHF.	Loop furosemide (Lasix) K+ sparing spironolactone (Aldatone) Thiazide hydrochlorothiazide (HCTZ)	Electrolyte depletion, dehydration.	Bladder dysfunction: increased urine output may result in frequency and possibly incontinence. Confusion: secondary to dehydration or electrolyte imbalance Falls secondary to dehydration
Narcotic Analgesics	Pain control	morphine, codeine meperidine (Demerol)		Bladder dysfunction: incontinence secondary to drowsiness, sedation. Bowel dysfunction: constipation Falls: increased risk. Confusion

Drug class	Used in	Examples	Action/Side effects of concern	Potential exacerbation of geriatric syndromes
NSAIDS Non-steroidal anti-inflammatory agents	Pain control	acetylsalicylic acid Non-selective diclofenac (Voltaren) ibuprofen (Motrin, Advil) naproxen (Naprosyn) COX II inhibitor celecoxib (Celebrex)	Increased risk of GI bleeding due to the inhibition of prostaglandin production.(less risk with COX II inhibitors). Fluid retention.	Confusion secondary to acute GI bleed or worsening CHF.

Structured Medication Review: Case Study

Mrs W. is a 91 year old community dwelling female. She lives in an assisted living facility and receives weekly assistance with bathing. Her previous medical history includes hypertension, osteoarthritis of the hips and knees, osteoporosis, urinary urgency. On a routine visit, she reports to the home care nurse 1-2 falls/week in past month. As part of her assessment, the nurse undertakes a medication review.

Medication Review

Medical conditions	Medications
HTN	Hydrochlorothiazide 12.5 mg daily
Osteoarthritis	Acetaminophen with 30 mg codeine PRN (takes 1-2 day) Celecoxib 100 mg po bid
Osteoporosis	Etidronate and calcium
Urgency	Oxybutinin 2.5 mg qhs
	Lorazepam 1 mg po qhs

Questions generated from the review:

- What medications might be contributing to the falls?
- Any recent changes?
- Are two medications for osteoarthritis needed for pain control?
- Why the benzodiazepine?

The nurse knew that both the lorazepam (a benzodiazepine) and the codeine could be contributing to the falls. In discussing the medications, Mrs. W. notes that there had been a recent change in medications. The lorazepam was prescribed 6 weeks prior for

difficulty getting to sleep, frequent waking episodes, pain and urgency at night. She was taking the acetaminophen with codeine and celecoxib due to painful knees. She had previously discussed the possibility of knee replacement surgery with her family physician.

Recommendations/Plan

1. Follow-up with family physician/primary prescriber re: pain control.
    - Change to plain acetaminophen RTC - many people can get adequate pain control with regularly administered acetaminophen.
    - Can she get a corticosteriod injection to the knee joint to bridge until a decision about surgery is made? Celecoxib might not be needed.
    - Discontinue lorazepam – taper down slowly.
    - Increase oxybutinin dose
2. Client education re: sleep changes with age, non pharmacologic approaches to sleep hygiene.

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CHAPTER 5

Paper 4: Post Operative Voiding Dysfunction in Older Adults Undergoing Hip Arthroplasty: A Feasibility Study[1]

Footnote:

[1]A version of paper has been prepared for submission to *JAGS: Journal of the American Geriatrics Society (Brief Reports)*

Post Operative Voiding Dysfunction in Older Adults Undergoing Hip Arthroplasty: A Feasibility Study

Geriatric syndromes, such as incontinence, falls and poor balance, after hip replacement have been linked to poor long term functional status (Bischoff-Ferrari et al., 2004). To date, urologic studies post hip arthroplasty have focused predominantly on short term post operative management with either indwelling or intermittent catheterization (Knight & Pellegrini, 1996; Oishi et al., 1995). A more comprehensive understanding of voiding function in this population would enhance symptom management throughout the post surgery period.

Reduced bladder contractility, decreased urine flow rate, and increased post void residual (PVR) urine are thought to occur with aging (Dubeau, 2006). In addition, chronic conditions known to affect bladder function, including diabetes, Parkinson's diseases, dementia and stroke, become more prevalent with age. Despite the potential for worsening urinary symptoms in hospitalized older adults, description of pre-existing and new onset LUTS is limited. In one geriatric rehabilitation population, 49% of patients post orthopedic procedure had new onset urinary incontinence (UI) at admission to rehabilitation, with only half regaining continence prior to discharge (Baztan, Arias, Gonzalez, & Rodriguez de Prada, 2005). Among hip fracture patients, UI was still present 24 hours prior to discharge in 23% of participants (Halm et al., 2003). Given that UI and other LUTS are acknowledged risk factor for falls, depression and social isolation, safety and post discharge management are issues of concern.

The most frequently studied urinary issue in the post arthroplasty population is urinary retention (UR), with rates reported from 0.8 – 54% (Brander, Malhotra, Jet,

Heinemann, & Stulberg, 1997; Izard, Sowery, Jaeger, & Siemens, 2006; Petersen, Collins, Selakovich, & Finkbeiner, 1991; Pettrine, Aamlid, & Cabanela, 1991). Potential risk factors for UR include anesthetic route (Parker, Handoll, & Griffiths, 2004), type and route of analgesic (Izard et al., 2006; Murphy, Stack, Kinirons, & Laffey, 2003), and gender (Izard et al., 2006; Murphy et al., 2003), often with inconclusive or conflicting results. Studies of comorbid disease as a risk factor have reported on severity of disease (Greenfield, Apolone, McNeil, & Cleary, 1993), preexisting musculoskeletal diagnoses (Levy, Levy, Snyder, & Digiovanni, 1995), or number of pre-existing diseases (Brander et al., 1997; Pettrine et al., 1991). Two studies specifically included diabetes, but neither found a significant association to UR (Michelson, Lotke, & Steinberg, 1988) or a broader range of urological complications (Izard et al., 2006). Methodological approaches in previous work also limit usefulness. For example, only Izard (2006) provided a volume based definition of UR, and several authors (Greenfield et al., 1993; Izard et al., 2006; Levy et al., 1995) used retrospective designs. Moreover, no studies have considered the broader context of voiding dysfunction in the older person, nor has a systematic pre and postoperative assessment been reported.

Thus, the questions addressed in this feasibility study were: what is the prevalence preoperatively and incidence postoperatively of voiding dysfunction in older adults undergoing elective hip arthroplasty, and are there differences between urinary symptoms, quality of life and quantified measures of voiding function before and six weeks after surgery. The purpose of undertaking the feasibility study was to assist the authors to determine if there is evidence to support the need for further research on urinary symptom management in perioperative and convalesant periods.

Method

The design was a prospective, observational, cohort study with measurement at two time points. The sample included males and females 65 years and older undergoing elective hip arthroplasty. Inclusion criteria were: 1) English speaking, 2) living within the health region, 3) MMSE equivalent of 24 or greater. Data collection took place in participant homes and on orthopedic wards at a large acute care hospital in Canada with 50-60 elective hip arthroplasties per month.

LUTS and related quality of life were measured using the American Urological Association Symptom Index Score (AUASI), a seven item instrument consisting of symptom severity questions (Barry et al., 1992), and a single symptom related quality of life (QoL) question. The tool has good internal consistency (Cronbach's $\alpha = 0.86$), excellent test-retest reliability ($r = 0.92$), is sensitive to change (Barry et al., 1992) and has been validated as a symptom severity index in both genders (Terai et al., 2004). The symptom score correlates with quality of life in men (te Slaa et al., 1997) and women (Scarpero, Fiske, Xue, & Nitti, 2003). Total symptom score is interpreted as mildly (0-7), moderately (8-19) or severely (20-35) symptomatic. The QoL question is scored as mild (0-1), moderate (2-4) or severe (5-6) impairment.

Incontinence was defined subjectively as self report of involuntary urine loss, and objectively as greater than 8 gram of urine lost on 24 pad test for both males (Moore, Allen, & Voaklander, 2004) and females (Groutz, Blaivas, & Rosenthal, 2000; Lose, Jorgensen, & Thunedborg, 1989; Versi et al., 1996). The pad test has been shown to be reproducible (Karantanis et al., 2005; Versi et al., 1996), and a single 24 hour test is considered sufficient to determine severity of urine leakage (Karantanis et al., 2005). For

the pad test, pre-weighed pads were provided to participants to be worn and changed as necessary for a 24 hour period. At the end of the test period, the pads were collected in sealed plastic bags and weighed. Those self-reporting incontinence were asked about stress/urge symptoms concurrent with incontinence. Post void residual urine (PVR) was measured using the BladderScan BVI 3000. Urinary retention was defined as a PVR greater than 200ml.

Initially, participants were recruited from one large orthopedic practice. After notification of surgery date, office clerks were to contact patients about the study. However, office staff reported that time constraints and a lack of patients meeting study criteria affected recruitment, so a second source of participants from the hospital preadmission clinic (PAC) was added. PAC staff provided names of patients willing to speak with the researcher. The researcher briefly provided further information and booked a home visit with interested individuals.

Preoperative home visits occurred between one day and three months prior to surgery. Informed consent, demographic information, relevant medical and surgical history, medication use, answers to continence questions and the AUASI were all were obtained. Participants were asked to void, and the PVR urine was measured and instructions for the 24 hour pad test provided. On the third post operative day, after the indwelling catheter had been removed (usually 24-36 hours after surgery), a hospital visit was made. The patient record was reviewed for: anesthetic/analgesic route, nursing and medical progress notes indicating voiding function post catheter removal, urinary tract infection, and use of anticholinergic or alpha-antagonist agents. At six weeks post surgery, participants were again visited in the home setting. Questions regarding bladder

function after surgery, including the need for catheterization, were asked and the continence questions, AUASI, PVR urine and 24 hour pad test were repeated. Those with persistent symptoms were referred to their family physician.

Data were analyzed using SPSS statistical software. Descriptive statistics were used to summarize demographic data, medical history, medication use, incontinence, questionnaire scores, and objective measures. The Wilcoxon Signed-Rank test, the non-parametric alternative to the paired t-test, was used to detect differences between pre and post surgery AUASI symptom or quality of life scores, PVR urine or 24 hour pad tests.

Results

Recruitment took place over six months (from September 2005 to February 2006). Data collection was anticipated to end in April 2006, but was extended until July 2006 because surgery for two participants was rescheduled. Names of 35 individuals were received from either office or PAC staff. Seventeen consented to participate, with 16 (9 males, 7 females) completing the study. One participant was lost to follow up.

Mean participant age was 73.56 years (males 74 years, females 73 years). All lived independently in their own homes. Five had diabetes and one had had a prior stroke. None reported Parkinson's disease or dementia. Four male patients had a history of benign prostatic hypertrophy: two had previously undergone transurethral prostatectomy, one was taking an adrenergic antagonist, and one was recently referred for urological consultation. Of the females, two reported pelvic organ prolapse, and four had previous anti-incontinence surgery. While almost all participants took medication daily, none took anticholinergics for urgency or other medications with anticholinergic side effects. Fifteen participants underwent primary hip arthroplasty, with one having a revision

arthroplasty. Eleven (73%) had spinal anesthetic, with the remainder receiving a general anesthetic.

Preoperatively, fifteen reported at least one urinary symptom, with the most prevalent being nocturia (14), urgency (9) and frequency (8). Post operatively, all participants reported symptoms: nocturia (15), urgency (10) and frequency (9) (Figure 1). Nocturia was the most common symptom. Four participants had no change in total AUASI score, four had a lower score postoperatively (fewer symptoms), and seven had higher scores (increased symptoms). Two of these individuals had a postoperative score considerably higher than the preoperative score (a change from 4 to 17 and 8 to 22), indicating significant symptoms. Postoperatively, mean AUASI scores increased for both genders (males from 5.44 to 6.78, females from 5.86 to 7.00). Mean scores nocturia, urgency, frequency and incomplete emptying increased post operatively (Table 1 and Table 2). Nocturia is reported separately as it was measured by frequency of episodes, rather than a Likert scale. Of symptoms which increased postoperatively, only nocturia approached statistical significance ($p=0.08$). Mean scores on intermittency, weak stream and straining decreased postoperatively.

Four males and three females reported involuntary urine loss preoperatively, with five (two males and three females) continuing to report this after discharge. One female preoperatively and one male postoperatively described continuous loss. All others described occasional loss. Preoperatively, stress type symptoms were associated with urine loss in one male and two females, and urge incontinence in two males and three females. Postoperatively, stress symptoms were reported only by the male participant, with urgency remaining for all five.

Preoperative and postoperative 24 hour pad test indicated incontinence in one male and one female, both of whom self-reported incontinence at both times. Preoperatively five and post operatively three additional participants reported leakage, but this was not confirmed during 24 hour pad test. PVR was not elevated in any participants at either time period.

Symptom related QoL indicated better urinary related QoL for six, five no change, and five had higher scores (poorer QoL). Three participants of the five with worsening QoL described extreme distress over increased symptoms. Each of these participants had an increased AUASI score as well, with two being the individuals with substantially different scores described previously. For one male participant, whose total AUASI score increased from four (mild) to 17 (moderately symptomatic), QoL changed from pleased (1) to mostly dissatisfied (4) related to increased frequency, intermittency, urgency and nocturia. For the female participant with an increase in AUASI from eight to 22 (severely symptomatic), QoL changed from pleased (1) to unhappy (5). She reported increased symptoms of incomplete emptying, frequency, intermittency and nocturia. The last participant, a female whose total AUASI went from seven to nine and QoL from pleased (1) to unhappy (5), reported increased symptoms of frequency, urgency and nocturia. All three were referred for follow-up with family physicians to rule out post catheter urinary tract infection.

Mean and median PVR increased for both genders, with increases larger for female participants than male. No participants had a PVR greater than 200ml. Four females had increases in PVR ranging from 43 to 157 ml, and increases for four male participants ranged from 10-114 ml. None of the changes were clinically significant.

Incidence of new onset voiding dysfunction in the immediate perioperative period could not be determined. UI and PVR residual urine post catheter removal were not documented for any participants on hospital records. Difficulty in initiating voiding post catheter removal was described in one participant's record, but follow up was not recorded. Further, two participants reported difficulty voiding post catheter removal to the researcher, but this was not documented. For most participants, time of catheter removal and first void or volume of first void could not be determined. At post hospital visits, there were no self reports of persistent new onset incontinence, need for catheterization or referral appointments.

Discussion

The aim of the study was to describe voiding dysfunction in older adults undergoing hip arthroplasty. Understanding bladder dysfunction and related issues can assist health care professionals in comprehensive discharge care and follow-up. Despite limitations in sample size, some key issues were identified: 15 (93%) had LUTS preoperatively; 3 (18%) had distressing symptoms at six weeks postoperatively; medical/nursing records contained little information on voiding status at admission or during hospitalization and no participants received information at discharge on potential for urinary tract infection.

Preopreratively, prevalence of UI was low among participants and none had urinary retention or elevated PVR. However, some symptoms were commonly reported by participants both pre and postoperatively, and assessment of LUTS and related QoL was crucial in reviewing individual participant situations. It is likely that prevalence and incidence of a number of common symptoms, rather than just UI or UR, is the important

aspect on which to seek further understanding. Urinary symptoms *including* frequency, nocturia and UI have been identified as a risk factor for falls in many settings (Oliver, Daly, Martin, & McMurdo, 2004; Voaklander et al., 2006), and UI is a prognostic factor in subacute (Yust-Katz et al., 2005) and post hospital (Halm et al., 2003) morbidity and mortality among older patients. In this study, three of sixteen participants reported post discharge symptoms of frequency, urgency, intermittency and/or nocturia as extremely distressing. All participants had undergone bladder catheterization, but none recalled being informed on urinary tract infection risk, symptoms, or management. As urinary tract infection is a risk factor for deep joint sepsis in people who have undergone joint arthroplasty (Della Valle, Zuckerman, & Di Cesare, 2004), this is a serious concern. Clinicians need to provide adequate discharge teaching regarding complications, including urinary tract infection, to arthroplasty patients. Further longitudinal studies are required to establish the time of onset, etiology and resolution of urinary symptoms.

Use of health record data in the research setting was problematic as voiding dysfunction was rarely recorded nursing or medical notes. Anecdotal notes kept by the researcher revealed that one female patient with preexisting incontinence had continued incontinence during hospitalization and the male with preexisting incontinence had worsening urgency, but these were not documented pre or postoperatively. Along with a lack of documentation of urinary issues, no incontinent participants were offered incontinence products by hospital staff. Lack of, or inconsistent, hospital documentation of urinary symptoms was previously described by Cheater (1993). This raises questions regarding attention to urinary function and knowledge of associated safety risks among health professionals. Assessment of urinary function should be incorporated into

documentation, and further research in this area should incorporate specific measurement of symptoms and function by a research assistant, rather than relying on documentation.

Variations in time between preoperative home visit and surgery date were due to differences in the length of time between PAC visit, surgery, and rescheduling of some cases. Time between notification of office staff, contact with patients, and surgical date varied. Additionally, although the manager reported that patients were seen in PAC within days of surgery, actual time was days to months. Future studies will need to be planned with a specific length of time between collection of preoperative and post surgery data to minimize introduction of confounding variables, such as health status change. Participants will need to agree to a recollection of preoperative data should their surgery be delayed. Additional costs for these visits would need to be anticipated.

Access to potential participants was challenging. Over 200 older adults underwent hip arthroplasty at the site during the study, but the researcher received only 35 names. Implementation of a provincial pilot project on joint replacement surgery at the same time reduced the potential pool. The initial request to recruit and collect data in PAC, but managers declined citing burden to patients and staff. Support and participation of managers and direct care staff in recruitment was critical as the university/health region ethics review board required a person not involved with the research, but with legitimate knowledge of the patient first obtain assent from the patient for the researcher to contact them. An alternative recruitment approach through the orthopedic surgeons' office was identified. Unfortunately this was not a fruitful approach because of staff burdern, and the hospital administration approved completing the recruitment in PAC.

Recruitment to clinical studies has become more complex as a result of privacy legislation. To diminish the potential for undue influence or coercion, and to protect privacy, restrictions on direct recruitment of participants by researchers has become the norm in Canada (Whittaker, 2005), the United States (Erlen, 2005) and the United Kingdom (Redsell & Cheater, 2001; Tod, Nicolson, & Allmark, 2002). Recruitment is increasingly dependent on intermediaries (Redsell & Cheater, 2001), often clinical staff or physicians in a position to identify potential participants. Researchers rely on these individuals to introduce the research and gain assent for contact. In this study, differences in perceived value of research may have limited recruitment by staff. Although encouragement was received from orthopedic surgeons and site administration to undertake the project, front line managers had to balance this with staff workload. For staff, recruitment was an add-on task and not a priority. As office staff had no knowledge of postoperative care, the study likely held little meaning for them. Inservice time with PAC nursing staff was not available, so information provided to them was limited. Clinical staff may also have acted as gatekeepers, determining which individuals should not be burdened with participation requests. The alternate to recruitment by staff is use of recruitment posters, or advertisements. Unfortunately, these relatively passive recruitment methods are less effective than face to face contact (Unson et al., 2004). In future studies, a multifaceted approach incorporating both written information for potential participants and discussion with staff regarding their role in obtaining gaining assent should be considered.

Finally, recruitment to this study and future studies may have been influenced by appeal. As the study was descriptive, with no direct benefits to participants, appeal may

have been limited. As well, the study dealt with urinary function, which prospective participants may have considered a taboo topic.

Conclusion

As it was a feasibility project, this study is limited by the small sample size and the voluntary, convenience nature of the sample. Participants in this study may not represent the population of all older individuals who undergo elective hip arthroplasty. However, the purpose in undertaking this study was to describe voiding dysfunction in older adults undergoing hip arthroplasty and set the direction for further research on LUTS in hospital and during convalescence. Given the lack of attention to LUTS among hospitalized older adults, yet the importance as risk factors for complications and poor outcomes post hospitalization, voiding dysfunction at the time of an acute event or hospitalization remains an area of important research. Knowledge of contributing factors to voiding dysfunction in older adults facing an acute intervention or event would assist health care professionals in managing symptoms and minimizing risks both in hospital, as well as in the perioperative and convalescent phases.

Table 5-1

Description of Participants Completing the Study N = 16

Descriptor	Male	Female	All
Gender	9	7	16
Age			
Mean	74	73	73.56
Median	75	73	74
Range	65-82	65-79	65-82
Living site			
At home	9	7	16
Supported living	0	0	0
Medial history			
Diabetes mellitus	2	3	5
Stroke/TIA	1	0	1
Parkinsons	0	0	0
Dementia	0	0	0
BPH (males)	4	N/A	4
Prostate cancer (males)	0	N/A	0
Pelvic organ prolapse (females)	N/A	2	2
Surgical history			
Prostatectomy (males)			
TURP	2	N/A	2
Radical	0	N/A	0
Anti-incontinence surgery (females)	N/A	4	4
Medications			
Anticholinergic	0	0	0
Tricyclic antidepressants	0	0	0
Antipsychotics	0	0	0
Antihistamines	0	0	0
Self report of urinary incontinence			
Pre operatively	4	3	7
Post operatively	2	3	5
Surgery			
Primary hip arthroplasty	8	7	15
Revision hip arthroplasty	1	0	1
Anesthetic route			
General	3	2	5
Spinal	6	5	11

Table 5-2

Participant Scores on Measures

Participant	Sex	Preoperative Measures				Postoperative Measures			
		AUASI (total)	QoL	Pad test (gms)	PVR (ml)	AUASI (total)	QoL	Pad test (gms)	PVR (ml)
1	M	4	1	15	33	17	4	20	23
2	F	14	5	41.9	19	6	4	94.9	176
3	M	2	2	2.2	0	5	1	2.2	0
4	M	2	0	1.7	0	2	0	1.9	114
5	F	3	2	2.2	0	4	1	3.8	57
6	F	6	3	3.2	0	4	2	0.2	0
7	M	11	3	1.9	0	14	3	0.9	0
8	F	8	1	0.6	58	22	4	1.7	101
9	F	17	4	182.1	37	Lost to follow up			
10	M	2	0	1.7	36	2	0	2.1	46
11	F	0	0	3	0	1	0	3.4	0
12	M	12	3	3.4	74	14	5	0.4	38
13	M	4	1	4.5	172	1	0	2.2	31
14	M	2	0	1.4	27	2	1	2.7	141
15	M	10	5	2.7	6	4	3	3.3	31
16	F	3	0	0.9	0	3	0	1.7	0
17	F	7	1	2.9	0	9	5	1.3	51

AUASI Total: mildly (0-7), moderately (8-19) or severely (20-35) symptomatic

QoL: mild (0-1), moderate (2-4) or severe (5-6) impairment

Figure 5-1: Number of participants reporting presence of specific urinary symptoms on the AUASI Score (N=16)

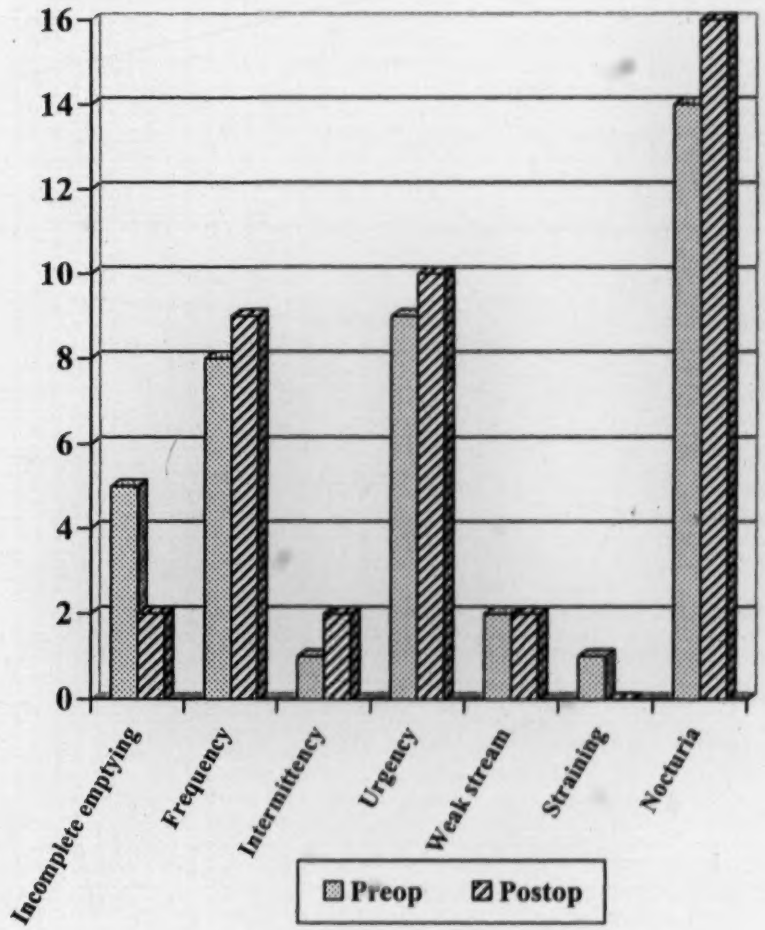

Table 5-3

Pre and Post Operative Scores on Individual AUASI Symptom Items

Symptom	Pre-operative	Post-operative	p*
Incomplete emptying			
Mean (SD)			
Median	0.44 (0.73)	0.50 (1.41)	
Range	0.00	0.00	0.666
	0-2	0-5	
Frequency			
Mean (SD)	1.00 (1.41)	1.38 (1.67)	
Median	0.50	1.00	0.233
Range	0-5	0-5	
Intermittency			
Mean (SD)	0.60 (0.25)	0.50 (1.41)	
Median	0.00	0.00	0.180
Range	0-1	0-5	
Urgency			
Mean (SD)	1.81 (2.17)	2.06 (2.21)	
Median	1.00	1.00	0.518
Range	0-5	0-5	
Weak stream			
Mean (SD)	0.31 (1.01)	0.25 (0.68)	
Median	0.00	0.00	1.000

Range	0-4	0-2	
Straining			
Mean (SD)	0.06 (0.25)	0.00 (0.00)	
Median	0.00	0.00	0.317
Range	0-1	0	

*Wilcoxon signed ranks test, 2 tailed, $\alpha = 0.05$

Score values: 0 (not at all), 1 (less than 1 time in 5), 2 (less than half the time), 3 (about half the time), 4 (more than half the time), 5 (almost always).

Table 5-4

Mean Scores on Individual AUASI Items: Nocturia

Nocturia episodes	Pre-operative	Post-operative	p*
Male			
Mean (SD)	2.11 (1.17)	2.44 (1.59)	
Median	2	2	0.41
Range	1-4	1-5	
Female			
Mean (SD)	1.71 (1.50)	2.29 (1.11)	
Median	2	2	0.10
Range	0-4	1-4	
All			
Mean (SD)	1.94 (1.29)	2.38 (1.36)	
Median	2.00	2.00	0.08
Range	0-4	1-5	

*Wilcoxon signed ranks test, 2 tailed, $\alpha = 0.05$

Scores range from 0 (do not get up at night to urinate) to 5 (up 5 or more times at night to urinate).

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CHAPTER 6

Conclusion and Recommendations

Conclusion and Recommendations

From literature reviewed in the previous papers and the feasibility study conducted, I have gleaned the following regarding LUTS in older adults during hospitalization and post hospitalization:

- Lower urinary tract symptoms are common among older adults, with UI being just one of these symptoms.
- A number of factors, including the aging process, chronic comorbid conditions, medications and sequelae of previous surgery, can contribute to LUTS in the older person.
- The presence of LUTS in older adults is associated with other geriatric symptom syndromes, including falls.
- LUTS appear to be under recognized and potentially under attended to in acute care and the transition between acute care and community settings. This may place the older adult at increased risk for serious sequela such as falls and infection in hospital and after discharge, and can negatively affect quality of life.

Clearly, for reasons of safety and quality of life, this is an area that should be addressed in both acute care settings and during the convalescent period. Incidence, prevalence, as well as short and long term outcomes related to LUTS in the vast array of populations of older adults who move in and out of the acute care system have yet to be elucidated. Contributors to the lack of attention to urinary symptoms in these settings are not yet clearly understood, and it is possible that a number of factors are involved. This may include the knowledge and skills of the health care professions around assessment and management of LUTS and the serious risks these symptoms pose, the taboo nature of

the subject inhibiting some individuals from bringing this to the attention of care providers, or the focus on single diagnoses rather than a more comprehensive approach to patient care. Based on the work I completed in the preceding papers of this dissertation, the following recommendations for theory, practice, education and research are advanced.

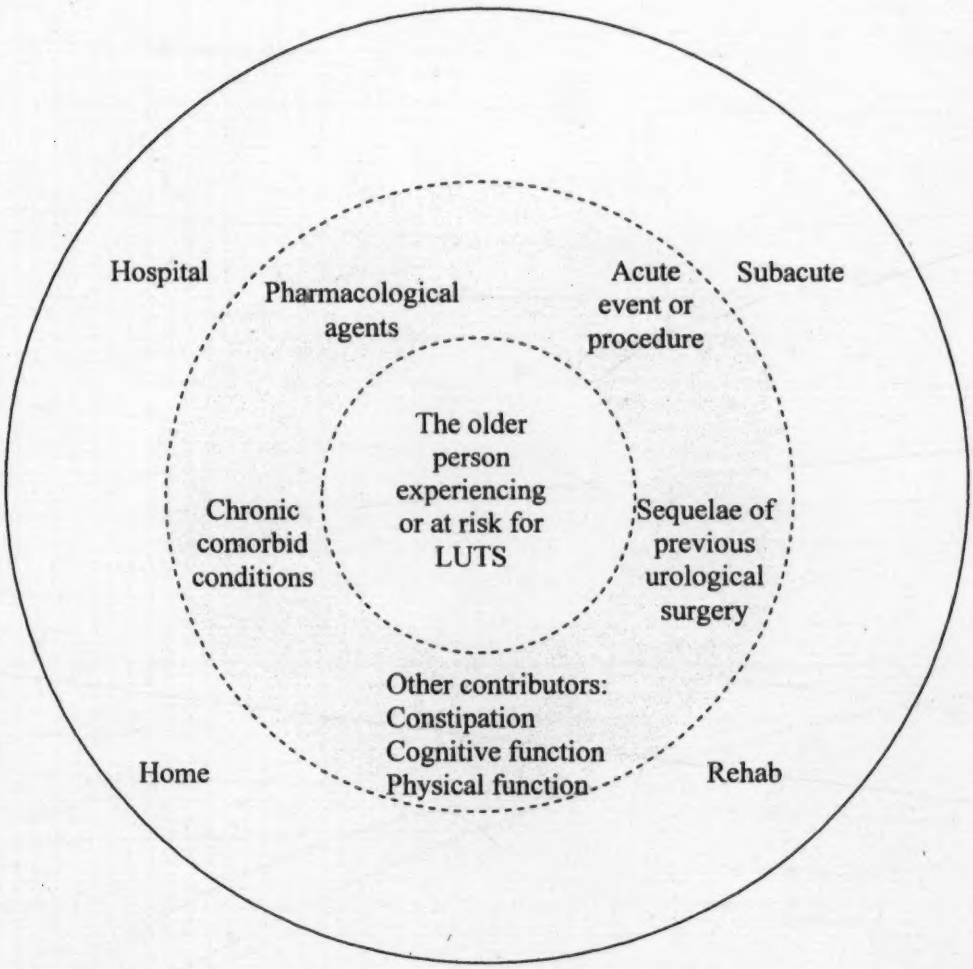
Recommendations for Nursing Theory Development

I would suggest that a model for understanding contributors to LUTS in older adults would be of use to nurses working in acute as well as post hospital settings. Assessment of voiding dysfunction and LUTS is complex and for experienced as well as novice clinicians, a framework could act as a practical guide to incorporating a broader focus to care, rather than a narrow and singular attentiveness solely on the reason for admission. As a basis for future research, the framework would be a beginning articulation of the linkages between the various influences on voiding function which include the individual, setting and a host of physiological and psychosocial influences. To this end, I have taken the visual model in which the connection of the papers in the dissertation is described (Figure 1-1), and further refined it (Figure 6-1)

In the centre ring, the focus has evolved through the development of this thesis from voiding dysfunction to the older individual with or at risk of developing LUTS. This removes a focus on a condition as the central concept, is more reflective on the individual experiencing changes which occur with aging, and anticipatory in terms of prevention.

Figure 6-1

Understanding influences on lower urinary tract symptoms in older adults



Contributors to LUTS are in the second ring, The older person experiences changes to the lower urinary tract as a result of aging, but urinary function may also be

influenced by pharmaceutical agents, prior urological surgery, the development of chronic health changes and the occurrence of an acute illness or surgical intervention. To this evolving model, I have added other contributors to impaired urinary function, including constipation, physical and cognitive function. Constipation, urinary tract infection and prior history of retention were predictors of elevated PVR urine in a case control study of elderly hospitalized women.(Tan, Lieu, & Ding, 2001). Fecal impaction, along with anticholinergic medications and diabetes, were risk factors for urinary retention in frail older people in rehabilitation setting.(Borrie et al., 2001) Constipation has the potential to contribute to poor emptying, especially in those who have other risk factors as well. As geriatric syndromes overlap one another, it is not surprising that UI can be predicted by cognitive and motor (physical) function impairment (Coppola et al., 2002). In older adults, impairment in lower body mobility increases risk for mild UI, and decreased strength is a predictor of severe UI, as are older age and having a proxy respondent, a situation which occurs with concurrent cognitive impairment (Jenkins & Fultz, 2005). In community dwelling older adults, UI was not a strong independent risk factor for death, nursing home admission, or functional decline, but it was suggested to be a marker of frailty (Holroyd-Leduc, Mehta, & Covinsky, 2004). A relationship between impaired cognition and urinary incontinence in hospitalized (Mecocci et al., 2005; Palmer, Baumgarten, Langenberg, & Carson, 2002) and nursing home (Brandeis, Baumann, Hossain, Morris, & Resnick, 1997; Coppola et al., 2002; Nelson & Furner, 2005; Palmer, German, & Ouslander, 1991; Sgadari, Topinkova, Bjornson, & Bernabei, 1997) populations has been described, although the exact nature of the relationship is not yet clear. Physical and cognitive impairments leading to or exacerbating UI are a part of

the so called *functional* type of incontinence. For some individuals, there may be no actual pathology of the urinary tract, although combination of LUTS arising from urinary tract changes as well as secondary contributors is possible. Future development of theoretical models should include the potential contributors outside the urinary tract.

In the outer ring are the various settings in which older adults might find themselves as a result of experiencing and acute illness or intervention. Although nurses may work only in one context, the individual patient moves back and forth through settings which make up a health care system. To attain the sometimes elusive goal of continuity of care, nurses need to envision patient care from the perspective of movement through a system rather than concentrate on single issues within a stationary environment. This broadens the perspective of assessment and care planning to integration of health history, function prior to hospitalization, symptom management and identification of education and follow-up referrals at discharge.

In summary, the following recommendation for nursing theory development is made:

1. Models and, potentially, mid range theories which draw from knowledge from a broad array of research from the fields of aging, urinary function and symptom management need to be developed to guide practice and research in nursing management of LUTS in older adults.

Recommendations for Nursing Practice

To decrease risk of adverse events and improve quality of life, I suggest that assessment and management of LUTS should be integrated into care for all older persons while in hospital and throughout discharge planning and convalescence. This includes

obtaining information on symptoms and management strategies which existed prior to hospitalization, documentation and implementation of evidence-based strategies for managing new onset LUTS, patient education and follow-up. Knowledge translation into practice settings is influenced by the relationship of the evidence in terms of research, clinical and patient experience; the context, including leadership and learning orientation of the organization; and the facilitation of change through persons with appropriate skills and knowledge (Rycroft-Malone, 2004). Moving towards a health care system that provides comprehensive care to seniors, including attention to LUTS, will not happen without careful planning. The following recommendations are made in as a starting point for this move:

1. Assistance for nurses in practice to integrate their own clinical experience with recent developments in assessment and management of lower urinary tract symptoms and continence care is needed. Knowledge and skill in the area of urinary incontinence assessment and management may be limited (Cooper & Watt, 2003), and this likely extends to other lower urinary tract symptoms as well. Opportunity for continuing education, clinical discussion and involvement in evaluation of care practices would be helpful.
2. Incorporation of the geriatric symptom syndromes, including LUTS, might be best achieved through integration of principles from comprehensive geriatric assessment into hospital care for seniors. Examples of programs where this has been done include the Acute Care of the Elderly (ACE) Unit approach (Kresevic et al., 1998; Palmer, Landefeld, Kresevic, & Kowal, 1994), Hospital Elder Life Program (Inouye, Bogardus, Baker, Leo-Summers, & Cooney, 2000) and Elder

Friendly Hospital (Parke & Brand, 2004). These programs attempt to address the context for care, as well as the provision of clinical specialists to act as resources for staff and facilitate the change process. Implementation of such a program requires a supportive administration and a planned strategy for evaluation of patient outcomes.

Recommendations for Nursing Education

As for nurses in clinical practice, geriatric content in undergrad nursing programs requires ongoing development to ensure new practitioners are prepared with the knowledge, skill and attitudes to provide appropriate, evidence based care and address safety needs of patients.

1. Nursing program curriculum should include theoretical and practice knowledge about the assessment and management of LUTS, utilizing current practice guidelines and providing clinical experience in continence clinics or with seniors in a variety of settings.
2. Opportunity for clinical faculty to expand their own knowledge and skills in this area should be provided. This could include individual learning, working with faculty and associate faculty with expertise in continence and gerontological nursing or attending conferences and workshops.

Recommendations for Nursing Research

Incidence, prevalence, as well as short and long term outcomes related to LUTS in the populations of older adults who move in and out of the acute care system have yet to be elucidated. Foundational research is required to fill this gap. As well, models and theories

of approaches to care for seniors with LUTS need to be tested through research. Specific recommendations for future research in this area are:

1. Given the risk of falls from urinary incontinence, and the inter-related nature of geriatric symptom syndromes, consideration should be given to adding measures of mobility and falls risk to studies on assessment and management of LUTS, as well as the contributors of chronic disease, pharmacological agents, sequelae of previous urological surgery and acute illness/surgery in future research.
2. Buy in to a research project must come from all levels of the organization in which it will occur. This includes the formal administrative approval, support from front line managers and informal interest in participation by direct care staff and clerks when they are required to be the first contact in the recruitment process. When designing future studies to examine voiding function and LUTS in older adults, consideration should be given to the ability of the staff to have the time to get patient assent for contact as well as their knowledge of the clinical issue under study.
3. A multifaceted approach to recruitment, with the initial permission for researcher contact through direct care staff, but also information posters and brochures and education for staff intermediaries should be used. Posters and brochures would need to approach the topic sensitively, as bladder function remains a taboo subject for many. These strategies need to be negotiated early with participating sites and agreement reached. Reluctance on the part of front line managers to have staff involved should trigger the researcher to consider alternate settings.

Summary

I have attempted in this work to take a scholarly approach to the examination of a clinical issue, that of assessment and management of lower urinary tract function in older persons as they move through the hospital and post hospital experience. Future direction and research will include examination of the prevalence of preexisting and incidence of new onset LUTS in medical and surgical populations of older adults, analysis of risk factors for development of new onset LUTS during acute care, and clinical trials of prevention and intervention strategies. This developing program of research is aimed at improving the safety and quality of life of older adults.

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APPENDICES

Appendix A: Recruitment Notice

Research Study

Post Operative Voiding Dysfunction in Older Adults Undergoing Hip Arthroplasty: Symptoms and Risk Factors

We would like to invite you to take part in a study on bladder function in older adults having hip surgery.

Older adults may have some bladder problems when they have surgery. We would like to find out more about these problems and who is at risk. The researchers are an Associate Professor of Nursing and a graduate student who is also a nurse. Both are at the University of Alberta Faculty of Nursing.

If you are interested in hearing more about this study, please write your name and phone number on the tear off form below and leave it here with the staff at your doctor's office. You will be contacted by the researcher at your home telephone number. More information on the study will be provided at that time. If you do not wish to be contacted, do not fill out the form.

If you have questions or concerns about this study, you or your family can call the researcher Kathleen Hunter at 492-4618.

Yes, I would like to hear more about this study.

Name: _____

Phone Number: _____

Appendix B
Telephone Interview Guide

May I please speak to: _____

My name is Kathleen Hunter, PhD student and researcher with the study Post Operative Voiding Dysfunction in Older Adults Undergoing Hip Arthroplasty: Symptoms and Risk Factors. You had put your name and telephone number on the list at the office of your orthopedic surgeon indicating you would like with further information about the study. Would you have time now to hear about this?

If no: When would be a good time to call you regarding the study?

If yes: The purpose of the study is to find out more about problems older adults sometimes have following hip surgery. If you agree to participate, the first visit will be several weeks before your surgery. I will visit you in your home for about 30 minutes. At that time I will ask you to sign the written consent for participation. I will ask questions about your medical history, medications and bladder function check for bladder emptying with a scanner. You will then be asked to wear pads for 24 hours as a check for any leaking of urine. I will come by and get the used pads from you the next day.

When you are in the hospital for your surgery I will stop by to check on how you are doing. I will also check in your chart for any bladder problems your health care team has recorded. The kind of medications you have been given will also be noted.

Six weeks after your surgery I will visit you again in your home for about 30 minutes to ask question about bladder symptoms after surgery and check for bladder emptying with the scanner. You will then be asked to wear pads again for 24 hours as a check for leaking of urine.

Although there are no direct benefits to you in taking part in this study, this study will help health care teams understand which patients may have bladder problems after hip surgery. We hope this will help in learning more for planning care in hospital and at discharge.

If you agree to participate, you have the right to withdraw from the study at any time. Withdrawal will not affect the care you receive in any way.

Do you have any questions?
Would you be interested in participating?

If not – thank for their time.

If yes – ask for a time that would be convenient for them to make the first visit.

Appendix C
Information Letter

Information Letter
Post Operative Voiding Dysfunction in Older Adults Undergoing Hip Arthroplasty: Symptoms and Risk Factors

Researchers
Katherine N. Moore RN PhD, University of Alberta Faculty of Nursing
Phone: (780) 492-1541
Kathleen F. Hunter RN NP MN PhD Candidate, University of Alberta
Phone: (780) 492-4618

Purpose of the study: Older adults may have bladder problems following hip surgery. We want to find out more about these problems and who may have them.

Study procedure: The first visit will be several weeks before your surgery. The researcher will visit you in your home for about 30 minutes. The researcher will complete a mental status check with you. If your score be below the score set for age and schooling no further study questions will be asked. The researcher will suggest that you see your family doctor for follow up. This screen does not mean you have any specific disease. Many things can affect the score, including side effects of medications, nutritional status and some medical conditions, so it is best to see your doctor for a check-up.

If the score is at or above the set score, the researcher will continue. You will be asked questions about your medical history, medications and bladder function. The researcher will ask questions on bladder symptoms. You will be asked to go to the bathroom to empty your bladder. She will then check for bladder emptying with a scanner. You will then be asked to wear pads given to you by the researcher for 24 hours. This is a check for any leaking of urine. The researcher will come by and get the used pads from you the next day. If the scanner had shown a lot of urine left in the bladder, the scan would be repeated. If it is still high, you will be asked to see your family doctor. If this happens, no further study visits will be made.

When you are in the hospital for your surgery the researcher will stop by to check on how you are doing. She will check in your chart for any bladder

problems your health care team has recorded. The kind of medications you have been given will also be noted.

Six weeks after your surgery the researcher will visit you again in your home for about 30 minutes. She will again ask you questions about your bladder symptoms after surgery. Once again you will be asked to go to the bathroom to empty your bladder and check for bladder emptying after with a scanner. You will then be asked to wear pads given to you by the researcher for 24 hours as a check for leaking of urine. The researcher will come by and get the pad from you the next day as before.

Risks: The scanner to check for bladder emptying uses sound waves. It is not an x-ray. The jelly on the lower part of your stomach for this test may feel cool and sticky. It is not painful. Please tell the researcher if you feel any discomfort.

Benefits: There are no direct benefits to you in taking part in this study. This study will help health care teams understand which patients may have bladder problems after hip surgery. This will help in planning care in hospital and at discharge.

Confidentiality: All information from the study will be held private except when legislation or professional codes of ethics require reporting. All records will be stored in a locked filing cabinet to which only the researchers have access. These will be kept for a period of five years after the study and then destroyed. The consent forms and list of people in the study will be kept separate from the information collected. Your name, or the name of your doctor, will not be on any reports. The information from this study may be presented at conferences or published. Your name or any information that would identify you will not be used in these reports.

By signing the consent form you give permission to the researchers to access any personally identifiable health information in the hospital record as deemed necessary for the study. A follow up study may be done in the next five years. If you agree with being contacted in the future for the follow up study, you would be asked again at that time for your consent.

You have the right to withdraw from the study at any time. Withdrawal will not affect the care you receive in any way.

Questions or Concerns: If you have questions or concerns about this study, you or your family can call the researcher Kathleen Hunter at 492-4618, Dr. Moore at 492-1541 or contact the Patient Concerns Office of Capital Health at 407-1040.

Appendix D
Consent Form

Title of Project: Post Operative Voiding Dysfunction in Older Adults Undergoing Hip Arthroplasty: Symptoms and Risk Factors

Researcher Information

Principal Investigator/Supervisor: Dr. Katherine Moore (780) 492-1541
Assistant Professor, University of Alberta, Faculty of Nursing
Co-Investigator/ PhD Candidate: Kathleen F. Hunter (780) 492-4618
University of Alberta, Faculty of Nursing

Consent of Subject

	Yes	No
Do you understand that you have been asked to be in a research study?		
Have you read and received a copy of the attached information sheet?		
Do you understand the benefits and risks involved in taking part in this research study?		
Have you had an opportunity to ask questions and discuss the study?		
Do you understand that you are free to refuse to participate or withdraw from the study at any time? You do not have to give a reason and it will not affect your care.		
Has the issue of confidentiality been explained to you? Do you understand who will have access to your records, including personally identifiable health information?		
Do you want the investigator(s) to inform your family doctor that you are participating in this research study? If so, please provide your doctor's name: _____		
Do you agree to be contacted within the next five years for a follow up study?		

This study was explained to me by: _____

Date: _____

I agree to take part in this study.

Signature of Research Participant:_____

Printed Name: _____

Witness (if available): _____

Printed Name: _____

I believe that the person signing this form understands what is involved in the study and voluntarily agrees to participate.

Researcher: _____

Printed Name: _____

* A copy of this consent form must be given to the subject.

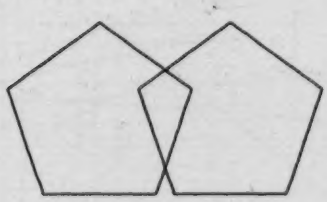
Appendix E

Mini-Mental State Examination and Cutoff Scores

Participants_____ Age____ Education level_____

Max score	Score	
Orientation		
5		What is the (year) (season) (date) (day) (month)?
5		Where are we: (address) (floor) (town/city) (province) (country)?
Registration		
3		Name three objects. (BALL, FLAG, TREE). Then ask the participant all three after you have said them. Then repeat them until she/he learns all 3. Count trials and record.____
Attention and Calculation		
5		Spell the word WORLD backwards. Alternatively do serial 7's.
Recall		
3		Ask for the 3 objects repeated above. Give 1 point for each correct.
Language		
2		Name a pencil and watch
1		Repeat the following: "No ifs, and or buts"
3		Follow a 3 stage command "Take the paper in your right hand, fold it in half, and put it on the floor"
1		Read the following and do what it says: CLOSE YOUR EYES
1		Write a sentence (1 point)
1		Copy a design (1 point)
30		Total Score

CLOSE YOUR EYES



Age and Education based cut-off scores for MMSE

Education in years	Age in years	60-64	65-69	70-74	75-79	80-84	85+
0-4		19	18	19	17	16	14
5-8		22	23	23	21	21	17
9-12		25	25	24	24	21	22
13+		26	27	25	25	25	24

Adapted from Iverson (1998) and Crum, Anthony, Bassett & Folstein (1993)

Appendix F

Participant _____ Date_____

American Urological Association Symptom Index Score (AUASI)

	Not at all	**Less than 1 time in 5**	**Less than half the time**	**About half the time**	**More than half the time**	**Almost always**
Incomplete emptying Over the past month, how often have you had a sensation of not emptying your bladder completely after you finish urinating?	0	1	2	3	4	5
Frequency Over the past month, how often have you had to urinate again less than 2 hours after you finished urinating?	0	1	2	3	4	5
Intermittency Over the past month, how often have you found you stopped and started several times when you urinated?	0	1	2	3	4	5
Urgency Over the past month, how difficult have	0	1	2	3	4	5

you found it to postpone urination?						
Weak stream Over the part month, how often have you had a weak urinary stream?	0	1	2	3	4	5
Straining Over the past month, how often have you had to push or strain to begin urination?	0	1	2	3	4	5
Nocturia	**None**	**1 time**	**2 times**	**3 times**	**4 times**	**5 times or more**
How often did you most typically get up at night to urinate?	0	1	2	3	4	5
						Total Symptom Score

Quality of life due to urinary symptoms	**De-lighted**	**Pleased**	**Mostly satisfied**	**Mixed, about equally satisfied and dis-satisfied**	**Mostly dis-satisfied**	**Unhappy**
If you were to spend the rest of your life with your urinary condition the way it is now, how would you feel about that?	0	1	2	3	4	5
						Quality of Life Score

Appendix G
Data Collection Form – Preoperative Home Visit

Participant Number ____

Date_____

Age_____ (in years) Date of birth_____
Gender male_____ female_____
Living arrangement: ____ Home (house or apt) ____ Supportive living facility

History of age related conditions associated with voiding dysfunction
____ Diabetes mellitus
____ Stroke/TIA
____ Parkinson's disease/MSA
____ Dementia Type (if known)_____
____ BPH (males)
____ Prostate cancer (males)
____ Pelvic organ prolapse (females)
____ TURP (males)
____ Radical prostatectomy (males)
____ Anti-incontinence surgery (females)

Current use of anticholinergic medications (list names)
_____Anticholinergic
_____Tricyclic antidepressants
_____Antipsychotics
_____Antihistamines

Do you have involuntary urine loss? Yes_____ No____

If yes:
Does the loss occur during coughing, sneezing, or physical exertion including position change?
Yes_____ No____

Is the loss associated with a sudden, strong urge to void?
Yes_____ No____

Is the urine loss continuous?
Yes_____ No____

How often each week do you have a bowel movement? _____

PVR urine volume _____(in ml)
IPSS Symptom score_____ QOL score_____
24 hour pad test_____(in grams)

Appendix H
Data Collection Form – In Hospital

Participant Number ____

Date_____

Date of hip arthroplasty _____

Anesthetic approach
___General
___Spinal

Recorded voiding dysfunction after catheter removal
____difficulty voiding
____ PVR urine greater than 200ml
____urinary incontinence episodes

Management of voiding dysfunction
____intermittent catheterization
____reinsertion of indwelling catheter
____alpha-antagonist started

Labs
____ post catheter removal urinalysis
Bacteria ____yes amount_____ ____no

____post catheter removal urine culture and sensitivity
results_____

Treated for urinary tract infection? ____yes _____no

Post operative use of anticholinergic medications (list names)
_____Anticholinergic
_____Antipsychotics

Number of bowel movements recorded_____

Appendix I

Data Collection Form – Post Hospital (6 weeks post arthroplasty)

Participant Number ____ Date_____

Since your surgery, are you having to use any of the following to help manage your bladder at home?
____incontinence pads
____intermittent catheterization (self)
____intermittent catheterization (assisted) Who assists? _____
____indwelling catheter
____medication Name_____

Are you being seen in follow-up for this by any of the following:
_____urologist
_____family physician
_____home care

Do you have involuntary urine loss? Yes_____ No____

If yes:
Does the loss occur during coughing, sneezing, or physical exertion including position change?
Yes_____ No____

Is the loss associated with a sudden, strong urge to void?
Yes_____ No____

Is the urine loss continuous?
Yes_____ No____

How often each week do you have a bowel movement? _____

PVR urine volume _____(in ml)

IPSS Symptom score_____ QOL score_____

24 hour pad test_____(in grams)